IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	HON. DAN A. POLSTER
APPLIES TO ALL CASES	:	NO. 1:17-MD-2804

- HIGHLY CONFIDENTIAL -

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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February 19, 2019

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Videotaped deposition of MICHAEL DiBELLO, taken pursuant to notice, was held at the offices of Locke Lord, LLP, 200 Vesey Street, New York, New York, beginning at 10:29 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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VIDEOTAPE TECHNICIAN:
Henry Marte

ALSO PRESENT:
Janine K. Downing, Esq. - (via telephone) (Henry Schein)

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I N D E X
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Testimony of:

MICHAEL DiBELLO

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E X H I B I T S
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E X H I B I T S (Cont'd.)

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E X H I B I T S (Cont'd.)

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E X H I B I T S (Cont'd.)

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E X H I B I T S (Cont'd)

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E X H I B I T S (Cont'd.)

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NO.	DESCRIPTION	PAGE
Henry Schein DiBello-27	E-mail Thread 1/7/12 Subject, California Doctor Linked to Drug Deaths Arrested HSI-MDL-00115531-34	286
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Henry Schein DiBello-29	E-mail Thread 10/1/08 Subject, Doctor Faces Charges on Improper Distribution of Drugs HSI-MDL-00622415-17	297
Henry Schein DiBello-30	E-mail, 11/18/11 Subject, Legal Action & Attached Notice of Hearing HSI-MDL-005912178-86	303
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DEPOSITION SUPPORT INDEX

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Direction to Witness Not to Answer
PAGE LINE
None.

Request for Production of Documents
PAGE LINE
None.

Stipulations
PAGE LINE
None.

Questions Marked
PAGE LINE
None.

THE VIDEOGRAPHER: We are now on the record. My name is Henry Marte. I'm a videographer with Golkow Litigation Services.

Today's date is February 19, 2019. And the time is 10:29 a.m.

This videotaped deposition is being held at 200 Vesey Street, New York, New York, in the matter of National Prescription Opiate Litigation.

The deponent today is Michael DiBello.

All appearances are noted on the stenographic record.

Will the court reporter please administer the oath to the witness.

- - -

... MICHAEL DiBELLO, having been first duly sworn, was examined and testified as follows:

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EXAMINATION

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- - -
BY MR. MIGLIORI:
Q. Good morning, sir.
A. Good morning.
Q. My name is Don Migliori. I'm from a firm Motley Rice. I'm going to be asking you some questions today. Throughout the course of the day, I'm going to be handing papers over to you and your counsel asking you questions. Hopefully they're intelligible. If they are not, please stop me. If you don't understand what I'm asking, or if you can't hear me, I'll be glad to rephrase or slow down.
I ask that all your answers be verbal so the court reporter can take down your testimony. I'd also ask that in between my question and your answer, that you give your counsel some time to interpose an objection if necessary.
If you answer -- if you answer my question I'm going to assume that you've understood it. Is that okay

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with you?
A. Yes.
Q. And have you gone through this process before?
A. No. I've never been deposed.
Q. Okay. So if at any time you need to take a break, I'm happy to stop, I ask that it be after a full question and answer has been completed, and then we'll take a break. Otherwise we'll take a break about every hour or so. It's my intent to not go very long today.
And I'm hopeful that I can stick to that.
Could you state your full name and your address, please?
A. Michael DiBello, 397 Split Rock Road, Syosset, New York 11791.
Q. Okay. And what is your current job and job title?
A. My current job title is vice president, deputy general counsel, regulatory, at Aceto Corp.

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Q. What is Aceto Corp.?
A. Aceto Corp. is a chemical importer distributor of chemicals and pharmaceutical ingredients, nutritional products, industrial chemicals, agricultural protection products.
Q. Does Aceto have any products that are considered controlled substances?
A. Aceto has -- List 1 and controlled substance chemicals.
Q. Do they manufacture control substances or do they just supply chemicals?
A. Aceto does not manufacture any chemicals or ingredients. They only import and distribute.
Q. Okay. And does Aceto have any products that would be related to opiates?
A. No opioid products.
Q. Okay. Before Aceto, what was your employer and your job title?
A. Before Aceto, I worked at

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Henry Schein. I was the director of regulatory affairs at Henry Schein, Inc., in Melville, New York.
Q. And what years were you there?
A. I started at Henry Schein in 1996 and I left Schein at 2012.
(Document marked for identification as Exhibit Schein-DiBello-1.)
BY MR. MIGLIORI:
Q. I'm going to show you Exhibit Number 1. It's a copy for you and for your lawyer.
Copy 1 -- Exhibit 1 is simply the notice for today's deposition. You are here pursuant to this deposition.
In preparation for this deposition, did you have any meetings with counsel?
A. Yes.
Q. When were you first notified about this deposition?
A. I was notified about this

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deposition about a week or so ago, this particular, yeah.
Q. The day?
A. The day, yeah.
Q. Okay. When is the first time that you actually sat and substantively talked about your testimony, either by phone or in person with counsel?
A. Yesterday. We sat and spoke.
Q. Okay. Was that the first time?
A. We spoke prior to that.
Q. When did you speak prior to that?
A. I would say probably around two or three weeks ago.
Q. Okay. Was that on the phone or in person?
A. On the phone.
Q. Were any documents sent to you to review for today?
A. No.

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Q. How long was the phone call a few weeks ago?
A. The phone call was approximately a half hour or so.
Q. And was that with your counsel here today?
A. Yes.
Q. And the next time that you spoke with counsel about this deposition was yesterday?
A. Correct.
Q. And did you meet in person yesterday?
A. Yes.
Q. How long did you meet?
A. We met yesterday, 9:00 a.m. until -- it was around 3:00, maybe 3:15-ish.
Q. Okay. During that time did you review documents?
A. Yes.
Q. Did you review any testimony of other witnesses?
A. No.

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Q. Do you recall a gentleman by the name of Shaun Abreu?
A. Yeah. I recall Shaun.
Q. Did you either review testimony that Shaun may have given in this case or did you speak with him about your testimony in this case?
A. No.
Q. How about Mr. Peacock? Have you either reviewed any testimony of Mr. Peacock or discussed his testimony in this case?
A. I have not reviewed any testimony nor discussed any of his testimony.
Q. And other than the documents that counsel brought to you to review, did you have any documents of your own that you brought to counsel?
A. No.
Q. Did you retain any documents after you left Henry Schein in your position relative to your time at Henry Schein? And by documents, I mean

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documents that would be dealing with your regulatory responsibilities, particularly in the area of controlled substances.
A. I just want to make sure I understand the question.
Did I --
Q. I can rephrase it if you'd like.
A. Yeah, could you?
Q. Do you have in your possession now, still, since leaving Henry Schein any documents from Henry Schein relative to your roles in regulatory affairs as they relate to controlled substances?
A. I may have. I may have some documents that I --
Q. What kind of documents do you think you have?
A. Documents that I, you know, worked on, were, you know, my documents, work product.
Q. As you know work product is a loaded term. When you say work

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product, are you talking about documents related to actual litigation or documents that were maintained in the ordinary course of business?

A. No documents related to litigation. Documents that were maintained in the order -- you know, normal course of business.

Q. And did counsel ask you to bring those documents with you, to the extent that they were related to your job as director of regulatory affairs?

A. No.

Q. Are they in a place that's -- that you -- strike that.

Do you know where the documents are, are you able to gather those documents and produce those, if required by your counsel?

A. I would have to locate them. Yeah.

Q. Okay. Any -- so all the documents you reviewed yesterday for the six hours or so were documents that

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counsel brought to you?

A. Correct.

Q. I assume they were things like e-mails and PowerPoint presentations and various documents internal to Henry Schein?

A. Correct.

Q. Were there any external documents, documents from outside the company that you were asked to review to your knowledge?

A. I want to make sure I understand the question. When you say documents outside the company?

Q. Any documents that would be from -- that would have been maintained by somebody other than Henry Schein.

A. Maintained by someone other than Henry Schein or produced by someone other than Henry Schein?

Q. Either. If that's an important distinction.

MR. McDONALD: I'll shortcut this, Don, and represent to you

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that every document we showed him had a Henry Schein Bates number from this litigation.

MR. MIGLIORI: Okay. So every -- every document that he saw, you have produced to us?

MR. McDONALD: Correct. If it was from a third party, it was -- it's not like Buzzeo, for example, maintained in Henry Schein files.

MR. MIGLIORI: Right. Or Rannazzisi letters. Anything that --

Mr. McDONALD: Correct.

MR. MIGLIORI: Whatever you showed him, showed up in my production.

MR. McDONALD: Correct.

BY MR. MIGLIORI:

Q. And that's all I'm trying to get it.

Before we get started, whatever it is that you've looked at,

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I've had a chance to look at myself?

A. Correct. Yeah, I just wanted to make sure I understood the question.

Q. Sure. And you wouldn't be in a position to answer that, so that was a hard one.

A. Okay.

Q. Okay. Would you say you've never had a deposition taken of you before?

A. No.

Q. All right. I don't have -- do you maintain a current curriculum vitae?

A. No.

(Document marked for identification as Exhibit Schein-DiBello-2.)

BY MR. MIGLIORI:

Q. This is just a snapshot of your -- this is Exhibit Number 2 -- of your LinkedIn page.

A. Okay.

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Q. From what I can tell.
A. Okay.
Q. It says, "Michael DiBello, vice president and deputy general counsel at Aceto Corp. and Rising Pharma." This is you, correct?
A. Yes.
Q. And with Aceto, those dates are correct, October 12th, 2012, to present?
A. Correct.
Q. And your office is in Port Washington, New York?
A. Correct.
Q. All right. The period of time that we're going to be talking about today is your time at Henry Schein Inc. It says, "Director of regulatory affairs and regulatory counsel, April 1996 to 2012."
First of all, those are the correct dates of your employment?
A. Correct.
Q. Were you director the entire

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time?
A. No.
Q. Okay. What did you hire in as?
A. I hired in as the quality manager.
Q. And what responsibilities did you have as quality manager?
A. My primary responsibility was to develop and implement a quality management system to certify the company to ISO 9000 quality, the international ISO 9000 quality system standard, and to CE Mark their private label products, medical dental products for distribution -- they were already -- you know, selling worldwide.
But in 1996 there were new medical device directives that were being implemented that required the CE Mark certification for distribution into Europe. That was my initial --
Q. Do you recall which -- do you recall which medical devices they

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were?
A. I'm sorry?
Q. Which medical devices were they, that you were working on?
A. They were medical devices which included anything from the medical business -- excuse me. I have a sore throat. I apologize.
So, the medical devices included everything in the medical business, which ranged from masks, examination gloves, instruments, to dental devices, again, you know, anything that a dentist would use in their practice. Generally speaking, low risk devices. They didn't make drug-coated stents.
Henry Schein did not make -- again, let me be clear. Henry Schein did not manufacture these devices. They simply had their private label name on them.
Q. Gotcha.
Was that all of your

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responsibilities as a quality manager?
A. At that time, that was the -- that was my primary role.
Q. And that started in April of '96. How long did that last, that role?
A. Approximately two years. '96, '90 -- probably into three years.
Q. Sometime in 1999?
A. Yeah. Approximately 1999 my role expanded to include the regulatory function and compliance.
Q. Before we get to that, from 1996 to 1999, did you have any responsibilities whatsoever relative to controlled substances?
A. No.
Q. And during that period of time, did you have any responsibilities relative to regulatory compliance in the area of controlled substances?
A. No.
Q. Did you have any regulatory compliance responsibilities at all in the United States? I know that you had this

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European --
A. Right. No.
Q. Before we get to 1999, I want to drop really quickly to Underwriters Laboratories. It lists here from June of 1987 to April of 1996. Almost nine years you were at a company called Underwriters Laboratories?
A. Correct.
Q. And there you were a senior project engineer/lead quality auditor?
A. Correct.
Q. What were your responsibilities there?
A. My responsibilities at UL included quality system audits, to audit and certify manufacturers. And those audits included military standard quality system audits for the government, including independent third-party audits in accordance with the ISO 9000 quality standard, the international ISO 9000 standard.
Q. Same questions, during that

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period of time, from 1987 to 1996, did you have any responsibilities whatsoever relative to controlled substances?
A. No.
Q. In that period of time from 1987 to 1996, did you have any responsibilities relative to regulatory compliance, other than the ISO 9000 standards?
A. No.
Q. And your educational background is -- you have a BS in electrical engineering from NYU, correct?
A. At the time it was Polytechnic Institute. They were later merged into -- yeah, it was NYU.
Q. Okay.
A. Now it's all part of NYU, but --
Q. It wasn't NYU at the time?
A. It wasn't NYU at the time. It's now NYU.
Q. Okay. From there you went to UL?

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A. Correct.
Q. And then after you left Underwriters Laboratories, there's a two-year gap between 1996 and 1998 that's not accounted for, that I can see on this short bio.
What did you do in those two years?
MR. McDONALD: I'm sorry, where -- where are you looking at, Don? I don't see a gap.
MR. MIGLIORI: I'm sorry.
BY MR. MIGLIORI:
Q. I see that you left Underwriters in April of 1996 and you started law school in 1998. And I'm just asking you what happened between those two years.
MR. McDONALD: Okay. But his -- he shows that he is at Henry Schein in 1996.
MR. MIGLIORI: Okay.
THE WITNESS: I was working at Henry Schein.

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BY MR. MIGLIORI:
Q. Okay. So you got your law degree while you were at Henry Schein?
A. Correct.
Q. All right.
A. 1998 I went to Touro.
Q. Okay. So you went right from UL to Henry Schein. And then after two years, while you were still a quality manager at Henry Schein, that's when you started law school at Touro, correct?
A. Correct.
Q. Was that a part-time law school?
A. Correct.
Q. And you got your law degree in 2002?
A. Correct.
Q. And then it says, "Columbia Business School, Certificate in Business Excellence." What is that program, in 2008 to 2011?
A. That's a mini executive MBA program where you take X number of

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classes and courses. I think it's 24 credits over a period of time, two years or so. And you get a certificate from Columbia Business School for their -- this mini MBA program.
Q. Okay.
A. Executive -- they call it executive MBA program.
Q. You don't actually receive a masters in business administration, do you?
A. No. It's not a masters. It's a mini MBA program.
Q. Okay.
A. Executive MBA program, they call it, for executives.
Q. And is that the one that's actually in the business school, or is that one that's part of the journalism school?
A. I'm not familiar with the journalism school.
Q. Okay.
A. I think it's the business

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school.
Q. Okay. And you got a certificate in 2011 there, while you -- again you were still at Henry Schein?
A. Correct.
Q. And that I assume was part-time or evenings or something like that?
A. It was not evenings. It was -- they had credits that -- courses that were either two, three, four or week-long courses that you took during that period.
Q. Okay. And what did you study in particular in that business school?
A. There were courses on negotiation. There were courses on leadership. There were courses on management, communication, strategic leadership.
Q. Okay. So either -- in any of your educational experience, did you take any courses specific to regulatory

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affairs? Did you have any training whatsoever in regulatory affairs in your -- in your courses?
A. No.
Q. At Underwriters Laboratories, you had no experience or background in domestic regulatory affairs, correct?
A. Not domestic regulatory affairs.
Q. And by domestic, I mean the United States.
A. Correct.
Q. And for the first three years at Henry Schein from 1996 to 1999, you had no roles relative to regulatory affairs in the United States on any issue including on issues relating to controlled substances, correct?
A. Correct.
Q. All right. So we'll get back up to Henry Schein. So in 1999 your job title changed from quality manager to what?

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A. I believe it was director of quality or QA.
Q. Tell me how your responsibilities changed in that role.
A. The change was due to a promotion from manager to director level. And the -- the role basically changed in that it expanded from corporate quality management system certification to rolling out the ISO certification to Henry Schein's distribution centers.
Q. The ISO responsibilities up until this point had been for the international market, correct?
A. Correct.
Q. Did that change to domestic when you got this promotion?
A. Well, it -- the international certification relied on the domestic certification of Henry Schein corporate office.
What changed was the certification of the distribution centers. So the expansion of ISO 9000

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now became not just a corporate certification for the European market, but implementing a quality management system for Henry Schein's distribution centers.

Q. At this point in 1999, are you now -- in dealing with the distribution centers, are you now responsible for any issues relating to controlled substances?

A. 1999, no. I don't -- I don't believe so.

Q. Did you have any responsibilities relative to suspicious order monitoring systems or standard operating procedures, relative to controlled substances?

A. I don't believe so, not in 1999.

Q. How long did you hold that job as director of quality assurance?

A. I don't recall when my -- the exact time when -- when I was promoted to director of regulatory

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affairs. But probably within a few years after that.

Q. Okay.

(Document marked for identification as Exhibit Schein-DiBello-3.)

BY MR. MIGLIORI:

Q. Let me show you Exhibit Number 3.

Exhibit Number 3 is a document produced by Henry Schein. It's called the export compliance program corporate procedural manual.

A. Okay.

Q. Produced to us by Henry Schein. Did you review this in preparation for today?

A. No.

Q. It's not apparent -- well, if you look at the third page, there's actually a date on the bottom of a memorandum or even at the top, of June 21, 2006.

Do you see that?

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A. Yes.

Q. And then there's attached to that is an organizational chart that actually has a revision date of October 7, 2007.

Do you see that on the page?

A. Yes.

Q. Okay. First, before we get to the organizational chart, the Henry Schein Inc. export compliance program corporate procedural manual, what is that? What is the export compliance program?

A. The export compliance program was a manual procedural that we put in place to ensure compliance with export controls, regulations.

Q. Is it a reasonable assumption -- by export, it's referring to international shipments?

A. Yes.

Q. So this document primarily relates to international distribution of Henry Schein products?

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A. Yes.

Q. Would that include controlled substances?

A. I don't recall.

Q. Okay. If you go to the third page, there is an organizational chart. It has Henry Schein, Inc., senior advisory regulatory affairs organizational chart, and it says, as of July 10, 2007.

And it has you listed under L. David. Who is that?

A. Who is L. David?

Q. Yes.

A. That was my immediate supervisor, Len David.

Q. Okay. And was he your supervisor the entire time that you were at Schein?

A. No.

Q. When did he become your supervisor?

A. I don't recall the specific time. I don't remember exactly when.

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Q. Okay. So sometime between 1999 and 2007 you took on a role with regulatory affairs, correct?
A. Correct.
Q. Whenever that was, between those two dates, is that when Len David became your supervisor?
A. Correct.
Q. All right. And up until that point, you had no background in regulatory affairs, at least as it related to controlled substances, correct?
A. Correct.
Q. When you became a director of regulatory affairs, did you take on any training relative to issues concerning controlled substances?
A. Yes.
Q. When was that and what was the training?
A. The training was ongoing. We always attended seminars, conferences, regardless of whether it was controlled

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substances, hazardous materials, FDA, DEA. It was ongoing training all the time throughout my entire tenure.
The training consisted of conferences, seminars at trade associations, Food and Drug Law Institute, and general -- general training at, you know, it could be at a law firm, as well, for CLE credits. So it was all of the above, and again throughout my entire tenure.
Q. Fair to say --
A. There was no formal, you know, if you're looking for a formal college accredited curriculum, there was no formal college accredited program, per se.
Q. Is it fair to say that your training in regulatory affairs was on-the-job training?
A. It also included on-the-job training.
Q. Okay. In addition to the conferences and the trade association and

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the seminars?
A. Correct. That's correct.
Q. And by trade associations, did you attend HDMA conferences?
A. That's correct.
Q. All right. Any other trade associations that you can recall that you learned or were trained in the area of regulatory affairs?
A. Another trade association was the Health Industry Distribution -- HIDA, Health Industry Distribution Association. I was also a member of the Food and Drug Law Institute. I was also a member of the New York State Bar Association, food and drug law group, which also had conferences and seminars.
Q. Okay. Any of the documents that you think you have in your own possession, are any of those related to any of these conferences, seminars, didactic training sessions?
A. You mean like --
Q. Manuals, CLE handouts?

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A. I probably do not have any of those anymore just by virtue of the fact that they would be outdated.
Q. I don't keep mine either. Just curious.
This chart that's in front of you right now.
A. Yes.
Q. Is this, at least as of 2007, the regulatory scheme, the regulatory structure within your department?
A. Yes.
Q. So it has you directly under Len David. And then under you --
A. Excuse me.
Q. -- it has K. Reid, administrative assistant. Was that your administrative assistant?
A. Yes. Well, she supported the whole group, but she reported to me.
Q. Okay. Underneath that, there are five different branches that report to you. I want to start with

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Sergio Tejeda.
A. Okay.
Q. What were his responsibilities, and how did he -- what was he responsible to report to you?
A. At that time, Sergio Tejeda was responsible for the regulatory group at GIV, which was general injectables and vaccines, in Virginia, they were based. He was -- he had a group that was responsible for recalls and DEA and HAZMAT.
Q. Which, if it's represented here, which group that reported to him was responsible for DEA?
A. Well, there were individuals in his group that -- that had DEA responsibilities. And those individuals were Craig Schiavo, Brian Loiacono, Andy Tiller, and Mark Wilburn.
Q. Okay. The other one that seems to have been left off from the list under him is Schmidt?
A. Correct.

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Q. All right. Let's go through that. What were Tiller's responsibilities with respect to DEA compliance?
A. So Andy Tiller was based at GIV.
Q. What does that stand for?
A. General injectables and vaccines.
Q. Okay.
A. GIV was a distributor that we -- that Henry Schein acquired, so -- through one of the acquisitions. So she was the supervisor, the regulatory supervisor at GIV.
Q. Did GIV have any controlled substances or opiate distribution?
A. I don't recall.
Q. Okay. What about Wilburn?
A. Mark Wilburn reported to Andy Tiller as a regulatory specialist, assisting Andy basically on her regulatory responsibilities.
Q. So did Mark or Andy have any

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responsibilities to the best of your recollection relative to the Controlled Substances Act or controlled substances?
A. At some point in time, I don't recall the exact time frame, they did have -- I know Mark had some responsibilities with respect to controlled substances.
Q. Okay. Do you know when and what it was?
A. I don't remember the time period. But I believe Mark was conducting due diligence audits for Sergio.
Q. Tell me about Loiacono.
A. Brian Loiacono was a regulatory specialist, and he did some DEA audits and DEA functions for Sergio. But he also had other, let's say FDA and other regulatory responsibilities.
Q. The DEA audits that you recall, were they specific to suspicious order monitoring or controlled substances? I'm still talking about

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Loiacono.
A. Yeah, Brian's role with Sergio was doing -- I believe he was doing the regulatory due diligence audits for the DEA -- you know, DEA due diligence audits.
Q. Including controlled substances?
A. When you say including controlled substances, what do you -- what do you mean by that?
Q. The due diligence for compliance with the Controlled Substances Act?
A. Correct.
Q. All right. Have you seen any of those audits in preparation for today?
A. No.
Q. Tell me about Sadler.
A. Peter Sadler's primary -- his focus was on HAZMAT.
Q. Okay. You did mention him in reference to DEA compliance earlier.

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The only one we left out was Schmidt. I thought you did anyway.
A. Peter Sadler?
Q. Yeah. He didn't have any responsibilities relative to DEA compliance?
A. No, I don't recall.
Q. Okay. As manager, was Sergio Tejeda the primary person responsible for the DEA compliance?
A. Within the regulatory group he was the primary person.
Q. And the distinction I think you're making, I'm asking, is that there were some compliance responsibilities outside of your group in regulatory affairs, correct?
A. There were some compliance activities outside the regulatory department.
Q. And if I'm mischaracterizing this, please correct me, but there were some front line responsibilities within the verifications department that were

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separate and distinct from the roles within regulatory affairs, correct?
A. Correct.
Q. As the orders and the initial pends, and by pends, P-E-N-D-S, I'm -- I'm referring to anything that's triggering a potential for suspicious order. All of those were handled on the front line by the verifications department, correct?
A. Please restate the question.
Q. Sure.
The orders as they came in to Henry Schein for controlled substances particularly, I'm talking about Schedule II opioids, came first through the verifications department for purposes of detection or potential detection of suspicious orders. Is that a fair statement?
A. That's correct.
Q. Regulatory affairs only got involved with pended or suspicious orders if they escalated through the -- the

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verifications department, correct?
A. Correct.
Q. And during the period of time that we are talking about here in 2007, was it Shaun Abreu that was primarily responsible for verifications, do you recall?
A. I don't recall when Shaun became the primary person. It may have been 2007, but I don't remember that.
Q. But -- but in any event, there was a -- there was a verifications layer for suspicious order monitoring that existed separate and distinct from regulatory affairs?
A. That's correct.
Q. And whether something escalated from verifications to regulatory affairs, was a decision made -- at this time in 2007, was a decision made by the verifications department, correct?
A. Correct.
Q. That is, there was no

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electronic monitoring at this stage of orders such that there would be an automatic report of anything suspicious to your department, correct?
MR. McDONALD: Object to the form.
THE WITNESS: Electronic monitoring that would -- I'm not sure I follow the question.
BY MR. MIGLIORI:
Q. That's fine. If you don't understand, that's fine.
A. Yeah.
Q. So we'll go through sort of the history of -- of the suspicious order monitoring program.
But let me ask you more basically. When did you first get involved yourself with any responsibilities as it related to suspicious order monitoring programs at Henry Schein?
A. I don't recall the time period when I first initially got

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involved with suspicious order monitoring.
Q. Was it a component part of your responsibility when you became -- when you moved into regulatory affairs? Was it immediately part of your responsibility or oversight?
A. When I moved into regulatory affairs it would have become part of my responsibilities.
Q. Okay.
A. That's correct.
Q. But as you sit here today, you don't recall exactly when that was?
A. I don't recall the exact time period.
Q. We know it's some time before this 2007 flowchart, right?
A. Yes.
Q. I'm not going to have you go through this right now. But I'm going to mark it and I may go through it at a break.
(Document marked for

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identification as Exhibit Schein-DiBello-4.)
BY MR. MIGLIORI:
Q. Let me show you Exhibit 4. It's what's been produced to us as your personnel file.
A. Okay.
Q. Lots of nice things said about you in there.
The only thing I want to ask you about is, it appears that you applied for the job -- this is Exhibit Number 4 -- that you applied for the job in April of 1996, correct?
A. Correct.
Q. At that point your only professional experience was Underwriters Laboratories, correct?
A. Correct.
Q. Your start date was April 1st, 1996?
A. That's correct.
Q. I'll just get this out of the way now. On September 21st, if you

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go down to the page that ends with the number 203, the little Bates number on the bottom right corner. There is a --
MR. McDONALD: Hang on. He's not with you.
THE WITNESS: What page did you say?
MR. McDONALD: 203.
BY MR. MIGLIORI:
Q. 203.
A. 203.
MR. McDONALD: You got it. It's right here.
THE WITNESS: That says 183.
MR. McDONALD: It looks like 203. There you go.
THE WITNESS: Okay. Great. Thank you.
BY MR. MIGLIORI:
Q. Now, this appears to be the resignation letter, September 21st, 2012.
A. Correct.
Q. And that resignation was effective October 19, 2012, correct?

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A. Correct.
Q. And what was the reason for your resignation on that date?
A. I had an opportunity presented to me by Aceto Corporation.
Q. So you just sought a different position with a different company?
A. Correct. For a better opportunity.
Q. And have you looked at your personal file in preparation for today?
A. No.
Q. I may come back to that later. I may not.
A. Okay.
Q. For now it's part of our little record.
All right. Just quickly, in looking at Exhibit 3 again, the organizational chart, there are other branches of regulatory affairs that reported to you. Did Clancy have any responsibilities with respect to DEA or

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suspicious order monitoring?
A. No.
Q. Did Manning have any responsibilities with respect to the DEA or suspicious order monitoring?
A. No.
Q. Did Romano have any responsibilities with respect to the DEA or suspicious order monitoring?
A. No.
Q. How about anybody underneath Romano?
A. At this point in time in 2007, Tina Steffanie-Oak did not have any DEA responsibility. She was the FDA person.
Q. As you implemented the Buzzeo system over time, she became part of the DEA team, right?
A. Later on, yes, she became part of Sergio's DEA team.
Q. Okay. And then finally the Canadian regulatory affairs, B. Thornton, I assume had no responsibilities with

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respect to the DEA?
A. That's correct.
Q. Did this flowchart effectively -- other than people shifting around in different positions, was this essentially the structure of the department through the time of your departure in 2012?
A. No.
Q. What changed over time?
A. Don Manning reported to Len. He was moved over to Len.
Q. So he no longer reported directly to you. You reported directly to Len?
A. Correct.
Q. Did quality assurance continue to report to you?
A. Yeah. At some point in time, Maurizio Romano and the quality assurance team reported to Len. And then -- and then later he was moved back to me. So that -- that was a move there, too.

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And Al Clancy resigned. I don't know exactly when. But he resigned. And his function -- his direct report, Wesley Milton reported to Don. That changed.
Q. Is it a true statement that from the time that you took on responsibility with regulatory affairs through the time of your resignation, that Sergio Tejeda and the DEA compliance people reported to you?
A. That's correct.
Q. And you reported to Len David?
A. That's correct.
Q. Okay. In preparation for today, did you do anything to review the activity of Henry Schein relative to the county in which claims have been brought in this litigation; that is, Summit County, Ohio?
A. No.
Q. You're familiar with the obligations of Henry Schein to report to

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the ARCOS data over time, correct?
A. Correct.
Q. And that came under your department; that is, what -- let me restate that.
Did ARCOS reporting, was that a responsibility of regulatory affairs or verifications?
A. ARCOS reporting was the responsibility of verifications.
Q. Okay. So that was not part of your responsibility?
A. Nope.
Q. Suspicious order monitoring, was that regulatory affairs, verifications or both?
A. Suspicious order monitoring was primarily a responsibility of verification.
Q. Okay. What role, if any, did regulatory affairs play in that suspicious order monitoring program at Henry Schein while you were there?
A. Regulatory was involved in

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the engagement of Buzzeo to develop an enhanced suspicious order monitoring process, and to implement, to help coordinate and implement and facilitate those enhancements to our suspicious order monitoring process.

Q. Okay. So just briefly, if you will, what is Buzzeo and how did you interact with Buzzeo at the beginning?

A. Buzzeo is a consultant that Henry Schein used prior to my joining the company.

He was consulting, I would say, several years prior to joining -- prior to my joining the company.

Buzzeo was a former DEA agent. And we retained Buzzeo to help us with the DEA project and on occasion, you know, I mean, he did -- he did a lot. He did audits for us. He advised us in several different aspects with respect to DEA.

Q. So when you first got involved with regulatory affairs sometime

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before 2007, Buzzeo had already been consulting with Henry Schein --

A. That's correct.

Q. -- for suspicious order monitoring?

A. He was consulting with Henry Schein way before I took over regulatory.

Q. Okay.

MR. McDONALD: So let me -- let me tell you, just be sure he's done with his question before you are answering. You're doing pretty good. The last one you answered it halfway through his question.

THE WITNESS: Okay. Sorry.

MR. McDONALD: Just wait until he's done. He'll pause occasionally. He's trying to throw you off.

MR. MIGLIORI: I'll try to talk quicker so we can get to your answer quicker.

THE WITNESS: Okay. I

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thought you -- I thought you stopped.

MR. MIGLIORI: No, no, that's fine. That's going to happen. The more we talk conversationally, the more that happens.

THE WITNESS: Sure.

MR. MIGLIORI: Sometimes it takes somebody outside watching us to point it out to both of us.

THE WITNESS: Sure.

(Document marked for identification as Exhibit Schein-DiBello-5.)

BY MR. MIGLIORI:

Q. Let me show you Exhibit Number 5. This is a PowerPoint presentation that bears your name on the cover.

A. Yes.

Q. I'll tell you that from metadata, we're able to decipher that the date of this is November 2, 2009. Okay?

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A. Okay.

Q. Let me just show you. So Cegedim Dendrite you understand to be an iteration of Buzzeo?

A. That's correct.

Q. All right. So this is a presentation that bears your name. Do you recall putting this together?

A. Yes.

Q. Did you review this in preparation for today?

A. Yes.

Q. And so, when you're talking about Buzzeo and the consulting, we're talking about the same group here, correct, that you -- that you seem to have presented this presentation with, right? It's their watermark or their -- correct?

A. Correct.

Q. Do you recall giving this presentation, actually presenting it?

A. Yes.

Q. And what -- what was your

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audience? Who was your audience, the annual controlled substances conference?
A. So the audience -- Ron Buzzeo did conferences and seminars, as we discussed earlier. That was one of the training programs that we attended.
He gave annual -- at least once a year, sometimes twice, so the audience was distributors, manufacturers.
Q. This would have been your competitors in the market?
MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. Right? Other distributors?
A. Yes.
Q. So you're presenting at this conference with other distributors Henry Schein's approach to DEA compliance. Is that a fair generalization?
A. Yes.
Q. Okay. These were the topics. You gave a quick overview of the company.

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Is this -- was this accurate at the time, that Henry Schein was the largest distributor of healthcare products and services to office-based practitioners in the combined North American and European markets?
A. Yes.
Q. And that includes, obviously, controlled substances?
A. Yes.
Q. Customers include dental practices and laboratories, physician practices, and animal health clinics, as well as government and other institutions. Those were your clients?
A. Correct.
Q. Over 12,000 employees at the time. Business in 23 countries. And over $6 billion in sales. That was the size of the company?
A. Correct.
Q. The next slide you put here basically sets forth sort of the foundation of DEA compliance as it

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relates to controlled substances, correct?
A. Correct.
Q. This is the excerpt from the Controlled Substances Act that puts on the distributor the responsibility of designing and operating a system to disclose to the registrant suspicious orders of controlled substances, correct?
A. Correct.
Q. You wrote that "the regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system." So you were aware of the obligation of DEA -- DEA registrants like Henry Schein in their sole responsibility to design and operate suspicious order monitoring programs for their company?
A. Can you repeat the question?
Q. Sure. That statement, the -- "The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such

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a" -- "such a system."
That statement refers to Henry Schein, correct?
A. Correct.
Q. That is, designing and operating a system for Henry Schein suspicious order monitoring system was non-delegable. It was something that you had to do yourself, right?
A. That's correct.
Q. In reference to the December 2007 letter from DEA, are you familiar with what's referred to as the "dear registrant" letters or the Rannazzisi letters? Do you recall reading those?
A. Vaguely. In 2007.
Q. So the citation here to the December 2007 letter. Do you have a specific recollection of -- of having read that at the time, or been aware of it at the time?
A. I have a general recollection.

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Q. Okay. And this excerpt here, this is something that you pulled out from that letter for the purposes of this presentation to the trade association, correct, or you had it pulled?
A. I had it pulled out, yeah. I didn't prepare it.
Q. And then you go through some challenges that you felt. You thought this was an unclear requirement with respect to knowing your customer.
What -- what do you recall, if anything, was unclear about the obligations under the Controlled Substances Act to know your customer, if you can recall?
A. Do I recall what -- can you repeat that question?
Q. Yeah. Your first bullet point here says, "Unclear requirements with lack of guidance. Know your customer."
Do you recall why you put

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that bullet point, that there was -- there were unclear requirements with lack of guidance relative to "know your customer" obligation?
A. Okay. So the way the statute is written, it was not specific for a particular customer to determine whether an order could be, you know, deemed suspicious. And that was the -- so it was not specific. It was -- it was a very broad, very general requirement.
Q. Do you recall in any of the letters received in 2007 or 2006 a guidance from the DEA about what are some of the things that are deemed to be red flags or anomalies that need to be investigated for the "know your customer" obligations?
A. I recall that they -- there was a -- you know, in the letter there was some guidance offered.
Q. Okay. And again the date of this is November of 2009. By this point you said you were a member of the HDMA.

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Do you recall the guidance provided to Henry Schein and other distributors from the HDMA about the "know your customer" obligations, specifically in 2008?
MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. Do you recall that, that's my only question.
A. Not specifically, but --
Q. Do you recall that there was, in fact, a guidance that Henry Schein signed off of from the HDMA in 2008 relative to the DEA compliance best practices?
A. You said signed off on it?
Q. As a member of the HDMA.
A. I don't recall.
Q. Okay. We'll get into the specifics of the process. But I want to direct your attention to Page 11 right now, just for a timeline.
A. Okay.
Q. This is your PowerPoint. So

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I just want to sort of go through. Do you recall looking at this timeline in preparation for today?
A. Yes.
Q. All right. So in this slide that you prepared for this presentation, you have that the suspicious order monitoring project started in September of 2007. Is that the beginning of the implementation of the Buzzeo recommendations?
A. No.
Q. What is that date?
A. I'm not -- I'm not -- I'm not recalling what that date signifies.
Q. Shaun Abreu testified in this case as the person designated by Henry Schein to speak for the company relative to the suspicious order monitoring program in place. To the extent that his -- that he has a recollection of this and -- and what it signifies, at least at this stage, given your -- your current memory, would you

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defer to his testimony, his memory?
MR. McDONALD: Object to the form.
THE WITNESS: Would I -- I just want to make sure I understand the question.
Would I defer to his recollection?
BY MR. MIGLIORI:
Q. He's testified and was designated by Henry Schein as the person who will speak for the company, not just for himself --
A. Okay.
Q. -- on what these dates signify. You have not reviewed that testimony, have you?
A. No.
Q. All right. And as you sit here today, you personally don't have any information about what the suspicious order monitoring project start date means, is that fair to say?
A. Correct. I don't.

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Q. This is your slide, but you just don't recall as you sit here today?
A. I don't recall what that project start date means.
Q. Okay. In November of 2007, in your slide, it says, "Restrictions set up to prevent accounts from ordering products not normally used in their practice."
Do you recall a recommendation of Buzzeo or Dendrite, whatever the name was at the time, that there be an immediate standard operating procedure to prevent certain accounts from getting products based on practice type?
A. I don't recall that specific recommendation.
Q. Okay. But you put this in your slide presumably because there was a decision in November of 2007 to put in an immediate restriction on certain accounts, correct?
A. Well, I would -- you said

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immediate. It was -- it was -- it says here, "Restrictions set up to prevent accounts from ordering products not normally used in their practice." So that's -- that was implemented. I would -- I would agree that it was implemented as stated here on the slide.
MR. McDONALD: You okay?
THE WITNESS: It just went down the wrong pipe.
(Document marked for identification as Exhibit Schein-DiBello-6.)
BY MR. MIGLIORI:
Q. I'm going to show you Exhibit 6.
I'm just giving this to you for another historical --
A. Okay.
Q. -- look at it.
This is dated July 19, 2018, last year, from Jeff Peacock to Sergio Tejeda. And it's attaching another PowerPoint. And it has a little timeline

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there. It's on Page 2.
A. Okay.
Q. And it says, "History of Henry Schein's SOMs and 'know your customers' due diligence development."
A. Okay.
Q. It says here, "In 2008, Henry Schein suspicious order monitoring system was designed in conjunction with Buzzeo PDMA."
Is that consistent with your recollection, that the suspicious order monitoring system that was recommended and implemented in 2008 was that -- that was consulted to, at least, to -- by Buzzeo?
A. I'm sorry. The question was?
Q. I'll ask you again.
A. In 2008?
Q. In 2008, in this chart --
A. Right.
Q. -- it says, Henry Schein suspicious order monitoring system was

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designed in conjunction with Buzzeo. Is that consistent with your recollection?
A. In 2008, I just don't understand the significance of 2008. What --
Q. These aren't my documents.
A. Yeah, they're --
Q. I understand you --
A. -- not my documents either. That's why I don't understand the question, I guess.
Q. Well --
MR. McDONALD: Hang on. Hang on. One of you needs to talk at a time. Let him ask the question.
THE WITNESS: Sure.
BY MR. MIGLIORI:
Q. I'm just trying to give you some context. I am showing you in this first exhibit, Exhibit Number 5 --
A. Right.
Q. -- I'm showing you a chart that you actually presented to a trade

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association. And it talks about the start of the suspicious order monitoring program in September of 2007. And you told me that you don't recall that.
I asked you about whether you recall restrictions being set up to prevent accounts from ordering products not normally used in their practice in 2007, again, in your slide, and you said you don't recall that.
A. That's not what I said.
Q. Okay. You do recall it?
A. No. I said in response to your question, you said immediate.
Q. Okay.
A. I said I don't know what you mean by "immediate restrictions were implemented."
Q. Fair enough. I'll take the word out "immediate." Do you recall putting in those restrictions?
A. Yes.
Q. All right. Were those restrictions the recommendation of

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Buzzeo?
A. I don't recall the specific recommendation with Buzzeo.
Q. In December 2007, there is another reference to the DEA letter sent to manufacturers and distributors. Do you recall our earlier discussion about that letter?
A. Yes.
Q. And that's the letter from Joe Rannazzisi to all DEA registrants, correct?
A. Correct.
Q. We'll get into that a little later.
A. Okay.
Q. Going to this exhibit, which is from last year, and in giving the history of it, it talks about Henry Schein's suspicious order monitoring system being designed in conjunction with Buzzeo in 2008.
I'm simply asking, does this refresh your recollection of this start

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date that's in your chart in the earlier exhibit?
A. Yes.
Q. So is it fair to say, going back to your chart, that at the end of 2007, is when the Buzzeo system was first being implemented or being designed for Henry Schein?
MR. McDONALD: Object to the form.
THE WITNESS: No, I don't believe 2007 was an accurate reflection of when the Buzzeo system was designed.
BY MR. MIGLIORI:
Q. Okay. So what was the date that you put in your own slide that says, "Suspicious order monitoring project started"? What does that signify in your chart?
MR. McDONALD: Objection. Asked and answered.
THE WITNESS: I believe that date signifies a point in time

when some development and implementation activities were underway. But it does not reflect when the SOM enhancement project was initiated.

BY MR. MIGLIORI:

Q. Okay. So now you are talking about an enhancement project. Again, this is -- these are your -- this is your chart, where you've picked a date, and you call it an SOM project. Is that different from the enhancement project, or were you wrong about the date?

MR. McDONALD: Objection.

BY MR. MIGLIORI:

Q. I'm just trying to understand your chart.

MR. McDONALD: Object to form.

THE WITNESS: The chart says SOM project started. So that's -- that's the SOM project. I refer to it as SOM enhancements, because

that's what was the goal of the SOM project.

BY MR. MIGLIORI:

Q. Okay.

A. And the date, all I said was that the 2007 date merely reflects the fact that design, development, implementation, programming, was underway. But does not reflect the actual genesis of the -- of the project.

Q. Okay. I can't say I understand any more, but at least we can agree that your words are, "Suspicious order monitoring project started September 20, 2007"? Somehow that's what you chose to represent in this chart?

A. Correct.

Q. And Peacock chose to represent in his chart last year that the Henry Schein suspicious order monitoring system was designed in conjunction with Buzzeo starting in 2008. And you're saying that's inconsistent with your recollection?

A. No. I didn't say it was inconsistent. I said one talks about the project being designed in conjunction with Buzzeo, PDMA. And that's Peacock's characterization. And my chart has SOM project started in 2007.

Q. Okay. And Peacock says that the implementation of the suspicious order monitoring system was completed in 2009. That's in Exhibit 6. In your Exhibit 5, it seems that you also say that the, "New item setup process implemented," and you have a box around the October 1st to October 9th dates, "System completion." Do you see that?

A. Yes.

Q. All right. Okay. So can we agree that whatever project was underway in 2007 and/or 2008 in these two exhibits, you both agree that that project was operational and implemented in October of 2009? Is that a fair timeline?

A. Yes.

Q. In your exhibit you talk about a statistical approach, specifications were finalized and submitted in March of 2009.

Do you recall the process of coming up with statistical algorithms that were to be tested for implementation in this new suspicious order monitoring program?

A. Yes.

Q. Okay. And those were statistical approaches that were designed in conjunction with Buzzeo, correct?

A. Correct.

Q. And their testing and the standard operating procedures being revised and finalized, that all occurred through October of 2009 when they were -- when they were first implemented, correct?

A. Correct.

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

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Q. And then in 2012, according to Jim Peacock's chart, the suspicious order monitoring system was audited by Buzzeo in a collaborative effort with Henry Schein verifications, regulatory affairs, legal and internal audits. Is that another -- is that consistent with your recollection?

A. I don't recall 2012 SOMs audited by -- that statement, "SOMs audited by Buzzeo in collaboration with Henry Schein verifications, regulatory legal, and internal audit."

Q. You don't recall the Buzzeo audit?

A. I don't recall specifically the Buzzeo audit. I recall Buzzeo working with us throughout the entire process. If he conducted an audit throughout the process, which probably did, I mean, there was a lot of testing and, you know, validation going on. But I don't remember -- I don't recall the specific 2012 collaborative effort.

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Q. Okay. So it's in 2012 in September, or actually effective October 19th or something, that you left the company, correct?

A. That's correct.

Q. All right. And before we take a break, just to get this out of the way.

You didn't have any responsibilities or interactions with Henry Schein after you left the company, did you?

A. That's correct.

Q. I saw that you offered to help in the transition, but once you left the company, you lost -- or you no longer maintained any communications, contact, or interactions with either Henry Schein or Buzzeo with respect to Henry Schein's suspicious order monitoring program, correct?

A. That's correct.

MR. MIGLIORI: Why don't we take a break.

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THE VIDEOGRAPHER: All right. Stand by, please. Remove your microphones. Okay. The time is 11:49 a.m. Going off the record.

(Short break.)

THE VIDEOGRAPHER: Okay. We are back on the record. The time is 12:06 p.m.

BY MR. MIGLIORI:

Q. I want to try to fill in some of that timeline now with some specifics and some experience directly.

Let's start at the beginning.

So sometime in early 2000s when you first got to regulatory affairs, did you -- did you get there as director, did you go right into a director position?

A. When I got to regulatory affairs?

Q. Yes.

A. Yeah. I was director of

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quality.

Q. Right.

A. And then I believe the title was changed to director of regulatory affairs.

Q. Okay. And that's what happened some time between --

A. 1999.

Q. -- 1999 and 2007?

A. Yeah. Yeah.

Q. And it's when you became director of regulatory affairs that you first started to deal with the Controlled Substances Act and the obligations relative to DEA compliance, correct?

A. Correct.

(Document marked for identification as Exhibit Schein-DiBello-7 and Schein-DiBello-8.)

BY MR. MIGLIORI:

Q. This is Exhibit 7. It's just a statement of the Controlled Substances Act. Do you recognize that as

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the part of the Controlled Substance Act that governs the distributor's responsibility as it relates to designing and operating a system to disclose to the registrant suspicious orders of controlled substances?
A. Correct.
Q. It talks about informing the DEA in the area of suspicious orders when discovered by the registrant. You understood that to be an obligation under -- an obligation of Henry Schein to report suspicious orders when discovered?
A. Correct.
Q. And you see that this act was enacted in 1971?
A. Correct.
Q. So I assume for all relevant time that you were at Henry Schein, that you understood and appreciated this was the obligation, correct?
A. Correct.
Q. You also understood as the director of regulatory affairs that under

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the Act, "Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency," that that was the definition in part of suspicious orders?
A. Correct.
Q. As director of regulatory affairs at Henry Schein, you also appreciated that under that same act, Congress made certain findings about controlled substances? Were you aware that there were certain findings, congressional findings about controlled substances?
A. I don't recall the specific findings.
Q. Did you appreciate, while you were director of regulatory affairs at Henry Schein, that, "The illegal importation, manufacture, distribution and possession and improper use of controlled substances have a substantial and detrimental effect on the health and

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general welfare of the American people"? Were you aware of that?
A. Yes.
Q. And were you aware that in the scheduling of drugs, going back to 1970, that the Schedule II drugs were defined as, "A, the drug or other substance has a high potential for abuse"? Did you appreciate that as director of regulatory affairs?
A. Yes.
Q. Did you appreciate as director of regulatory affairs that a Schedule II drug was, "A drug or other substance, has a currently accepted medical use in treatment in the United States or currently accepted medical use with severe restrictions"?
A. Correct.
Q. Did you appreciate as director of regulatory affairs at Henry Schein that Schedule II drugs -- that, "Abuse of the drug or other substance may lead to severe psychological or physical

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dependence"?
A. Yes.
Q. And did you appreciate while you were director of regulatory affairs at Henry Schein that opioids were Schedule II drugs?
A. Yes.
Q. At some period of time, hydrocodone was a Schedule III drug -- actually, were you aware of the fact that hydrocodone was a Schedule III drug during the time that you were director of regulatory affairs at Henry Schein?
A. I don't recall.
Q. I was going to go through some documents chronologically that have your name.
(Document marked for identification as Exhibit Schein-DiBello-9.)
MR. MIGLIORI: The first one is Exhibit 9.
BY MR. MIGLIORI:
Q. Now when you first got to

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regulatory affairs, what did you understand the suspicious order monitoring program to be?

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

Q. Before we get to the document, what was in place at the time that you started for controlled substances?

A. When I started as director of regulatory?

Q. Yeah.

A. My recollection is that there was a suspicious order monitoring system in place to ensure that we detected suspicious orders and reported them accordingly.

Q. That system in place was a system that was day-to-day managed by the verifications department?

A. Verification department had a primary responsibility for that.

Q. Okay. And when you first

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got there, do you recall who was responsible for verifications at the time?

A. I don't recall who was responsible for verification at that time.

Q. What, if any, responsibilities did your department have relative to the suspicious order monitoring program in place when you became director of regulatory affairs?

A. My team would get involved when they had questions that the verifications group were not sure how to handle.

Q. Did regulatory affairs set any thresholds at that time when you first started as director?

A. No.

Q. Did regulatory affairs establish any definitions of what is a suspicious order?

A. No.

Q. Did regulatory affairs

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establish any definitions of what is a pended order?

A. No. When I -- when I took over the group --

Q. At the beginning.

A. At the beginning, no.

Q. And did regulatory affairs have any responsibilities with respect to the due diligence performed when onboarding a new customer at the time that you started?

A. At the time that I took over, no.

Q. Did regulatory affairs have any responsibilities with respect to "know your customer" obligations of an existing customer of Henry Schein when you took over as director?

A. I don't recall.

Q. Is it fair to say that relative to the suspicious order monitoring program that existed when you took over as director of regulatory affairs, that your department was there

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as a resource to verifications when they chose to use it?

A. Yes.

Q. Otherwise, the suspicious order monitoring program, to the extent it existed when you started as director, was managed, implemented, audited by the verifications team?

A. There's several parts to that question, all right. So managed by the verification team, that's -- that was their primary responsibility.

Implemented, yeah, I guess they would implement their, you know, procedures and practices.

Audited by the verification team, I don't recall.

Q. Okay. You've had a recollection that Buzzeo was already in place as a consultant for the suspicious order monitoring program at the time that you took over as director, is that -- do I remember that correctly?

A. So Buzzeo was a consultant,

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for all things DEA, when I took over.
Q. Okay.
A. Including the SOM.
Q. Okay. So were you aware of any audits at the time that you took over as director that were being performed by your department of the suspicious order monitoring program?
A. Audits? I don't recall audits.
Q. Do you recall whether Buzzeo had already or were in the process of doing any audits of the suspicious order monitoring program when you became director?
A. I don't recall.
Q. As you sit here today, is your first recollection of a change in the existing suspicious order monitoring program that you inherited when you became director, the first change of that was the change that we saw in the timeline, that is, at the end of 2007, beginning of 2008?

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A. The first change?
Q. The first change in the suspicious order monitoring program, yes.
A. 2007 being the first change, is that the question?
Q. No. Let me repeat it.
You became director sometime before 2007.
A. Yes.
Q. I assume we are talking about a matter of two, three, or four years.
A. I would say probably more than that. I would say closer to 2000, 2001, '2. The early 2000s --
Q. Okay.
A. -- when I became --
Q. From 2002 until 2007 when you first -- the first date you put on the SOM project in the timeline we discussed there --
A. Okay.
Q. -- were there changes made to the suspicious order -- suspicious

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order monitoring program at Henry Schein that you can recall?
A. I can -- I can't recall specific changes. But I recall that it was a -- it was an ongoing evolutionary process.
Q. Okay. And was that evolutionary process being managed by regulatory affairs or by the verifications department?
A. It was a collaborative effort --
Q. Okay.
A. -- where both teams worked to continuously, you know, review and monitor the -- the process.
Q. And what role did you play, if any, in that process?
A. My role as the director was to provide the resources and support for the verifications team, to make sure that Sergio and his team, the regulatory team, would be able to support the verifications group.

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Q. And do you recall any ways in which Sergio and his team supported the verifications group in the time frame from 2002 to 2007 specifically to change the system? Do you recall anything specifically?
A. I don't recall anything specifically. But I know that there -- there are a lot of meetings, and a lot of interaction and a lot of discussion about the suspicious orders monitoring system.
Q. Did you participate in those discussions?
A. Yes.
Q. Were there regular meetings in that time frame?
A. There were meetings. There were -- there were lots of meetings with the verifications group and the IT group.
Q. Okay. And when did -- when did the -- did you -- strike that.
In those meetings, was it the verifications department that was -- that was relying on Sergio Tejeda's team

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for regulatory support?
During that period of time was it the verifications team that was operationally implementing the system?
MR. McDONALD: Object to the form.
THE WITNESS: During that time was the verification team implementing the system, the suspicious order monitoring system?
BY MR. MIGLIORI:
Q. Yeah.
A. Yes. They -- they -- the verifications team implemented the system. It was -- yeah.
Q. What resources or support would Sergio Tejeda be giving to them in that time frame?
A. The support would be regulatory technical support in the form of helping them to decide, for example, if this order was suspicious or not.
If this -- you know, at some

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point in time, there was a lot of activity and support with the consultant, Buzzeo. So that's another form of support between Sergio and the verification team.
Q. Was it the regulatory affairs department that retained Buzzeo, that chose to retain Buzzeo?
A. The regulatory team was the primary interface with -- with Buzzeo and made the decision to -- to retain Buzzeo.
Q. Other than what we saw today, which referenced 2007-2008 as the suspicious order monitoring program designed in conjunction with Buzzeo, are you aware of any other Buzzeo changes to the suspicious order monitoring program prior to 2007?
A. I'm not aware of specific changes, but I recall that the -- the Buzzeo engagement occurred before 2007. And again, I would -- I would -- you know, I would call Buzzeo, Sergio would call Buzzeo any time there was a

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question. So there was -- there was -- again, you know, we had a constant interaction with him on a regular -- not a regular, you know, daily basis, but on an occasional basis when we had a question about a DEA issue or a suspicious order monitoring -- suspicious order.
Q. Okay. Let me show you Exhibit 9 that I've already given you. This is an e-mail that was copied to you. When you deal with -- deal with e-mails, you start at the bottom and go up.
A. Okay.
Q. That's the way the chains work.
But this is January of 2007. And it's from Donna Remondino to you and others. At that time what did Donna Remondino do?
A. Donna worked in the verifications group.
Q. She wrote to you and said, "Trib called."

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Who is Trib?
A. Trib is a programmer, he worked in IT.
Q. Okay.
A. He's a IT programmer.
Q. "Trib called to inform me that they will be purging the control drug files and we will only have access to five years of history. I wanted to make sure prior to this being done that the DEA and state does not require longer history on file. I know we get requests to pull information longer than five years, but I am not sure what is our requirement. Trib will wait to do the purge on regulatory findings. Thank you for your help."
Do you recall her reaching out to you for this issue?
A. I don't recall the specific issue. Again, there were -- there were lots of questions between the verification and -- and the regulatory group.

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Q. Is this one of the ways in which verifications used regulatory affairs as a resource?
A. Yes, yes.
Q. In response to that, Sergio Tejeda, who at this point in January of '07 was reporting to you, correct?
A. Correct.
Q. Sergio responded copying you, saying, "Donna, purging drug files older than five years is acceptable and in compliance with DEA regulations and company policy. For future reference on recordkeeping for controlled substances products, I'm attaching a copy of the corporate record retention policy. Please ensure we maintain controlled substances records accordingly."
Do you recall that that was the policy at Henry Schein, to keep controlled substance drug files for five years only?
A. I don't recall specifically the five-year policy. But I know we had

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a policy.
Q. Do you know why -- do you know why Henry Schein maintained a five-year policy, purpose behind it?
A. Do I know why Henry Schein maintained a policy?
Q. A five-year --
A. Five-year --
Q. -- record retention policy.
A. No, I don't. I don't know why it was five years.
Q. We've talked a lot in other depositions about the -- the databases and the computer systems. At this time, is the JD Edwards, is that the name of the system?
A. JD Edwards.
Q. Was that in place?
A. Yeah, I think that was the name of the system. Sounds right.
Q. Did regulatory have any responsibilities with respect to setting the record retention policy or decisions to purge records?

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A. The record retention policy was set by legal.
Q. That's -- is regulatory part of legal or is that a separate department completely?
A. At what point in time are you referring to?
Q. Let's start with 2007.
A. In 2007, I don't recall the exact date, but I believe at that time period, regulatory was part of legal. There was a point that regulatory was not part of legal. So there -- there was a transition. When -- when David was reporting to legal.
Q. We have been advised that transactional records were purged in 2009.
Do you recall that being the case?
A. Transactional records were purged in 2009?
Q. Mm-hmm.
A. I don't recall that. I

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don't -- I'm not familiar with that.
Q. Were you part of any decision to purge any records that might relate to transactions or DEA reporting requirements in 2009 or at any time?
A. No. I was not involved.
(Document marked for identification as Exhibit Schein-DiBello-10.)
BY MR. MIGLIORI:
Q. I'll show you Exhibit 10: Exhibit 10 is a document received from Henry Schein called The Suspicious Monitoring System Meeting Confidential.
It's October 10, 2007. The attendees include folks from your team, Sergio Tejeda and Craig Schiavo, right?
A. Yes.
Q. Andy Tiller and Mark Wilburn, they reported to you as well, correct?
A. Indirectly through Sergio.
Q. Are these all regulatory people?

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A. Are these all, on the attendees?
Q. Yeah.
A. Maggie was verification. Maggie Wilding was part of the verifications team. Patrick Hannahoe was the IT team. Jaysari Pal was also part of the Patrick's team, IT.
Q. It says here that as the October 10, 2007, minutes of a meeting, confidential meeting. It says, "During this meeting it was decided that the suspicious monitoring system would take top priority with IS over all of the regulatory projects."
Is IS information systems?
A. Yes.
Q. IT department?
A. Yeah, yes. Same, yeah.
Q. "IS agreed to start figuring out how the system should be set up immediately and will supply regulatory with the specialty codes."
Do you recall in October

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2007 beginning a suspicious order monitoring system that involved Henry Schein's internal information systems?
A. I don't recall the specific meeting.
Q. Is it -- do you recall that prior to this date, that the suspicious order monitoring program at Henry Schein was not IT based?
MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. It wasn't automated.
A. Prior to 2007?
Q. Correct.
A. I don't recall that.
Q. The next line of the minutes of the meeting says, "The system needs to be able to set thresholds and flag all suspicious orders."
Does this refresh your recollection that a system was being implemented and designed as of October 2007 to create an automated system to set

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thresholds and flag suspicious orders at Henry Schein?
MR. McDONALD: Object to the form.
THE WITNESS: I don't recall.
BY MR. MIGLIORI:
Q. So as you sit here, you just don't recall either way. You don't recall this being true or untrue, correct?
MR. McDONALD: Object to the form.
THE WITNESS: I don't recall it being true or untrue.
BY MR. MIGLIORI:
Q. This minute -- the minutes go on to say, "Also during the meeting we ran through Bob Williamson's recommendations and what we discussed in the first meeting on 9/20/07, so that IS and GIV had an understanding of what was discussed in the previous meeting, as well as what we are trying to do, so that

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our systems are in compliance with DEA."
Do you recall Bob Williamson at Buzzeo?
A. Let me just correct my previous statement.
You asked if I recall this as being true or untrue?
Q. Yes.
A. I don't recall this as being true.
Q. Okay. Well, let's unpack that.
The -- this memo -- you'll agree with me that this -- these minutes of this meeting, of folks that reported to you, suggest that a system needs to be able to be set up to set thresholds and flag suspicious orders. That's what the document says, correct?
MR. McDONALD: Object to the form.
THE WITNESS: Correct.
BY MR. MIGLIORI:
Q. Do you believe that to be an

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untrue statement, that this system needed to be designed in October of 2007?
MR. McDONALD: Object to the form.
THE WITNESS: Can you repeat the question?
BY MR. MIGLIORI:
Q. Sure. These minutes of this meeting of folks that report to you said a few things. One, that it was decided that a suspicious monitoring system would take top priority with the IS department over all regulatory projects.
To the best of your recollection, was that a true statement then?
A. 2007. I don't recall.
Q. Okay. The -- the minutes of this meeting of your staff says, "Information systems agreed to start figuring out how the system should be set up immediately and will supply regulatory with specialty codes."
Do you recall that to be a

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true statement in 2007?
A. I don't recall.
Q. These folks who worked for you also reported in minutes of their meeting in October of 2007, that the "system would need to be able to set thresholds and flag all suspicious orders."
Do you recall that to be true in October of 2007?
A. I don't recall.
Q. The next sentence talks about a man by the name of Bob Williamson. Do you remember Bob Williamson of Buzzeo?
A. Yes, I remember Bob.
Q. Did you have interactions with him?
A. Yes.
Q. You knew him well, is that what you said?
A. No, I -- I said I knew Bob Williamson.
Q. Okay. And you understood

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that he was one of the consultants?
A. Yes.
Q. In fact, he was one of the lead consultants of Buzzeo, correct?
A. He was one of the consultants.
Q. Okay. These minutes of the folks that work for you in October of 2007 reference the fact that during the meeting, this group ran through Bob Williamson's recommendations and what we discussed in the first meeting of September 20, 2007, so that the information systems and the GIV department had an understanding of what was discussed in the previous meeting, as well as what we are trying to do so that our systems are in compliance with the DEA.
Do you recall that to be a true state of affairs as of July 10, 2007 at Henry Schein?
MR. McDONALD: Object to form.

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THE WITNESS: I don't recall.
BY MR. MIGLIORI:
Q. All right. Consistent with the timeline that we looked at before that you had in your PowerPoint presentation, it was around September 20 of 2007 that you reported to the trade association along with Buzzeo that Henry Schein started its SOM project.
Do you recall that?
MR. McDONALD: Object to the form.
THE WITNESS: Point of clarification. This was the Ron Buzzeo annual meeting, not the trade association.
BY MR. MIGLIORI:
Q. Okay. On the front page of that, it -- it said the 7th Annual. I thought you said it was the trade association. I thought you said you reported to some of your competitors and -- and other distributors?

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A. Right. But this was -- this was a Cegedim Dendrite annual controlled substance conference, not a trade association.
Q. Okay. So it was Buzzeo's conference --
A. It was Buzzeo's conference.
Q. But -- but a bunch of different distributors were there?
A. There were -- there were distributors.
Q. It was -- it wasn't a trade association apparently.
A. It wasn't a trade association.
Q. But you did present at that conference, that, in fact, in September of 2007, Henry Schein started the SOM project.
MR. McDONALD: Object to the form. Mischaracterizes the document.
BY MR. MIGLIORI:
Q. Right? Well, you can read

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the timeline --
MR. McDONALD: Correct. It doesn't say A.
BY MR. MIGLIORI:
Q. What does it say?
A. It says, "SOM project started."
Q. Okay. And you understand that to be the one that Buzzeo was consulting on, correct, in that Buzzeo presentation that you're making?
A. Correct.
Q. Okay. So if we get back to this exhibit, Number 10 in front of us, does this refresh your recollection that as of the time you started this SOM project in September of 2007, that the suspicious order monitoring program was not implemented through the Henry Schein information system at that time? That it was not an automated system as of September of 2007.
MR. McDONALD: Object to the form.

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THE WITNESS: I don't understand what you mean by automated system. We -- we had a computer system that identified thresholds.
So when you say automated system, it doesn't clearly describe the -- the system at 2007. Because there was a system in place, and -- there was a computer system in place with respect to thresholds.
BY MR. MIGLIORI:
Q. All right. Well, I'm definitely not trying to put words in your mouth. And I'll try my best to stick to what's on this Exhibit Number 10 sitting in front of you, okay?
But to do that, I'm going to refer you back to -- is it Exhibit 3. Can you just look at the front page of your timeline, the one that's in your hand? What's the exhibit number?
A. Exhibit 5.

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Q. All right. Exhibit 5. In your PowerPoint that you prepared and you presented to Buzzeo's conference, you actually picked a date of 9/20/2007. Do you see that?
A. Yes, I didn't -- I didn't pick the date. I didn't prepare --
Q. You presented the date.
A. I presented it, correct.
Q. And in that it says, "Suspicious order monitoring project started."
That's what your presentation said, correct?
A. That's what it says.
Q. All right. Now, I'm going to bring you to Exhibit Number 10. Exhibit Number 10 talks specifically about a meeting that you had with Bob Williamson, that is you being Henry Schein, on the same date, 9/20/2007. And the purpose of that meeting, it was discussed that what we were trying to do, that our systems are in compliance with

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the DEA.
Will you agree with me at the very least that the meeting referenced in this confidential minutes on October 10, 2007, shares the same date as the date the somebody picked for you as the beginning of the SOM project?
A. That's correct.
Q. All right. Will you also agree with me that the folks that report to you were -- boil down to a document that reflects the minutes of this meeting, where they say, first, it was decided that the suspicious monitoring system would take top priority with the informations systems department over all other regulatory products -- projects.
You'll agree that's what it says?
A. Correct.
Q. All right. And you have no reason as you sit here to doubt that that was now a priority of your regulatory team with verifications, the folks at

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this meeting, correct?
A. I think that this meeting captured what -- what was already a -- an ongoing evolutionary project. And this just reflects at that point in time what they documented was already in place. Meaning, a priority and a project.
Q. Okay. Without putting words in your mouth, you'll agree with me that this group said that the suspicious monitoring system would take top priority with IS over all other regulatory projects.
That's what they report about?
A. That's what they say.
Q. And you would have received these minutes, correct, as the -- as the supervisor to this group?
MR. McDONALD: Object to the form.
THE WITNESS: I don't recall.
BY MR. MIGLIORI:

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Q. Okay.
A. -- receiving the minutes.
Q. These -- this group, including Sergio Tejeda and others that reported to you, said that the information systems agreed to "start figuring out how the system should be set up immediately and will supply regulatory with the specialty codes."
So you agree with me at least that this group believed that this system needed to be set up immediately and figure out how to start figuring out how the system would be set up?
A. Correct.
Q. All right. And then that this group said that this system that needed to start immediately, that they needed to figure out, "needed to be able to set thresholds and flag all suspicious orders," that that was the priority at the time in October of 2007?
MR. McDONALD: Object to the form.

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THE WITNESS: That's what the -- that's what it says.
BY MR. MIGLIORI:
Q. And by reference to Bob Williamson and the prior meetings on September 20, 2007, this group is reporting out that the whole purpose of starting this project, figuring out how the system should be set up immediately, was in order to try to get the systems in compliance with the DEA. That was the purpose of creating this priority, correct?
MR. McDONALD: Object to the form.
THE WITNESS: That's what it says.
BY MR. MIGLIORI:
Q. Okay. You were not at this meeting, from what it appears on the face of this document, correct?
A. That's correct.
Q. All right. And you don't know whether they shared with you the

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minutes of the meeting from this date, correct?
A. Correct.
Q. But Sergio Tejeda, Craig Schiavo, Andy Tiller, Mark Wilburn, reported to you directly, correct?
A. Not directly. Sergio reported to me directly. Craig, Andy, and Mark reported to Sergio.
Q. Who then reported to you.
A. Who reported to me.
Q. All right. And is it a reasonable reading of this memorandum that the information systems, the automation within Henry Schein to date, was not set up to set thresholds and flag all suspicious orders yet?
MR. McDONALD: Object to the form.
THE WITNESS: I don't recall that.
BY MR. MIGLIORI:
Q. Okay. Now, around this same time, there was an HDA meeting with the

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HDMA meeting with the DEA. This is in Exhibit Number 11.
(Document marked for identification as Exhibit Schein-DiBello-11.)
BY MR. MIGLIORI:
Q. Do you recall ever attending a meeting with the DEA or the HDMA?
MR. McDONALD: Object to the form.
THE WITNESS: There were several meetings with HDMA. They would meet regularly with their membership. So I attended those meetings, not all of the meetings, but I would attend some of the meetings.
BY MR. MIGLIORI:
Q. If you look at the last page of this document which is called -- the document is called "The draft summary of HDMA-DEA meeting, October 16th and 17, 2007. Not for external distribution."
There is a list of

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attendees. And as part of the attendees, it lists Mike DiBello for Henry Schein, and Sergio Tejeda. Do you see that?
A. Yes.
Q. Do you recall attending this meeting?
A. Yes.
Q. Do you recall where it was?
A. No.
Q. All right. Let's go through it.
Suspicious orders. Do you recall that a subject matter of this meeting included suspicious orders?
A. Yes.
Q. Do you recall the DEA distributor initiative employee Kyle Wright speaking at this meeting?
A. I don't recall.
Q. Do you know who Kyle Wright is?
A. No.
Q. It says under suspicious orders, "Kyle Wright joined the meeting

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and provided DEA's presentation on suspicious orders."
Do you recall seeing that presentation?
A. I don't recall.
Q. Mr. Wright highlighted DEA's position that "wholesale distributors should conduct a more aggressive form of customer due diligence in addition to reporting."
Do you recall that being a concern in 2007?
MR. McDONALD: Object to the form.
THE WITNESS: I don't recall.
BY MR. MIGLIORI:
Q. Your -- you do recall that when you became director of regulatory affairs, that the "know your customer" obligations existed, right?
MR. McDONALD: Object to the form.
THE WITNESS: When I became

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director of regulatory affairs, I don't recall when the "know your customer" standard became effect -- or -- became effective specifically.

BY MR. MIGLIORI:

Q. All right. You know that the HDMA has recognized that the "know your customer" obligations always existed within the Controlled Substances Act obligations, don't you?

MR. McDONALD: Object to the form.

THE WITNESS: I -- you're asking if I know that HDMA always recognized "know your customer" standard?

BY MR. MIGLIORI:

Q. Yes.

A. I don't know that.

Q. Okay. This -- these minutes go on to say, "DEA also wants distributors to assess orders and stop them before they are filled if there is a

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reason to be suspicious, and expects wholesale distributors to thoroughly evaluate orders, the dispensers themselves, the dispensers' customers."

Did you appreciate, in October of 2007, that that's what the DEA expected of distributors?

MR. McDONALD: Object to the form.

THE WITNESS: Yes.

BY MR. MIGLIORI:

Q. "Kyle went so far as to discuss having a distributor's employee take a look at the dispensing site's physical location and watch for suspicious activity."

Were you aware that the DEA in October of 2007 was telling distributors that part of knowing your customer was on-site inspections?

MR. McDONALD: Object to the form.

THE WITNESS: Yes.

BY MR. MIGLIORI:

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Q. "When asked if these customers weren't DEA registrants and what steps did the DEA take to evaluate them before registration, Kyle made it clear that the DEA didn't have the resources to inspect or otherwise follow up on all registrants."

Did you understand, at least in October of 2007, that the obligations to inspect and know the customer were those of the distributors, not the DEA?

A. Yes.

Q. "Kyle also offered to act as an" -- "as an information conduit in the event that any distributor terminated a pharmacy or clinic customer based on suspicious orders."

Were you aware the DEA was a resource to Henry Schein in the event that it needed further guidance on any particular act or suspension?

MR. McDONALD: Object to the form.

THE WITNESS: Yes.

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BY MR. MIGLIORI:

Q. "He offered to notify all other distributors, than an unnamed distributor" -- I think it's supposed to be that an unnamed distributor -- "had terminated an account. That is, he offered to serve as a resource to share information among distributors about terminated accounts because" -- "because of suspicious orders."

Were you aware of that?

A. Yes.

Q. And then the response of the members of the HDA, according to these minutes, included the observation that "the view was that the DEA is expecting distributors to perform a significantly enhanced form of customer due diligence."

Did you understand in October of 2007 that the DEA expected that the due diligence be conducted in a significantly enhanced way from the way it had been to date?

A. Yes.

Q. Did you understand in October of 2007 that the DEA expected distributors to develop a proactive stop-shipment order monitoring model relative to suspicious orders?
A. Yes.
Q. And did you appreciate that the DEA expected distributors to expand their controlled substances reporting, that is, to be more inclusive if there was a doubt or question?
MR. McDONALD: Object to the form.
THE WITNESS: Can you restate that last question?
BY MR. MIGLIORI:
Q. Sure. Did -- did you appreciate in October of 2007 that the DEA expected distributors to expand their reporting of suspicious orders in the event that there was a question?
A. Yes.
Q. More information is better?
MR. McDONALD: Object to the

form.
BY MR. MIGLIORI:
Q. Correct?
A. More information is better?
Q. In the context of reporting suspicious orders.
A. Yes. I understood that.
Q. Then it says here, "Attendees expressed a number of concerns, including: The systems that DEA appears to expect are expensive and require IT and other expertise that is currently invested in other regulatory efforts, electronic pedigree systems."
Was that the experience of Henry Schein, that is, in having and attending this meeting with Kyle Wright, that the concern about better due diligence and more reporting and proactive stop-shipment monitoring, that it was going to be a costly IT endeavor for Henry Schein, do you recall if that was one of the concerns of the company?
A. I don't recall that as being

a concern.
Q. You'll agree with me though that at least based on the minutes that we just saw of the group that reported to you, that at this time, it seemed that Henry Schein decided to, in fact, going back to Exhibit Number 10, decided in fact to get their IT department actively involved in setting up and figuring out how to come up with the suspicious order monitoring system that could set thresholds and flag suspicious orders?
MR. McDONALD: Object to form.
BY MR. MIGLIORI:
Q. Whether it was expensive or not, Henry Schein actually proactively engaged its information systems department, at least according to these minutes?
MR. McDONALD: Object to the form.
THE WITNESS: Yes.
MR. McDONALD: Are you

moving to a new document?
MR. MIGLIORI: What's that?
MR. McDONALD: Are you moving to a new document?
MR. MIGLIORI: I think so.
MR. McDONALD: Why don't we take a lunch break.
THE VIDEOGRAPHER: Remove your microphones. The time is 1:58 p.m. Off the record.
- - -
(Lunch break.)
- - -
THE VIDEOGRAPHER: We are back on the record. The time is 1:49 p.m.
- - -
AFTERNOON SESSION
- - -
EXAMINATION (Cont'd.)
- - -
(Document marked for identification as Exhibit Schein-DiBello-12.)

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BY MR. MIGLIORI:
Q. Mr. DiBello, let me show you Exhibit 12. Now, as I understand the way it worked between regulatory affairs and verifications, the relationship with Buzzeo was mostly facilitated through regulatory affairs, is that fair?
A. Correct.
Q. And in 2005, you were the director of regulatory affairs, correct?
A. In 2005, I believe I was the director of regulatory. I don't remember the exact date when it happened. But it's -- 2005 seems correct.
Q. Okay. And so if Buzzeo did a report in 2005, then it's something that you would have at least received, if not been the recipient of?
A. Correct.
Q. In front of you, Exhibit 12, is a Buzzeo report dated September 16, 2005. And it references Henry Schein and an executive summary on the top page from a visit from Kathleen Malone, project

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manager from Buzzeo. Do you recall Kathleen?
A. Yes.
Q. And what did you understand her role to be?
A. She was the person that was going to be our primary point person that Buzzeo selected for this project.
Q. Okay. So in 2005, you would have interacted directly with her as Buzzeo was reviewing the suspicious order monitoring procedure and process?
A. I don't recall interacting directly with her. I'm sure I had probably a meeting with her, but I wouldn't say I interacted with her on a regular basis.
Q. You'll see that in the executive summary, they talk about how Dr. Schein, in 2002, conducted a study averaging all orders for each product placed over one years time to determine the significant threshold for each product cumulative for six months. Did

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you understand that to be the then existing methodology for setting a threshold for controlled substances?
A. Yes.
Q. That data -- that the current system was based on that data, modifications having been made, and new products added since the 2002 study, and at the entry of the threshold is a manual process conducted by the verification team. Is that consistent with your recollection that, from 2002 through 2005, thresholds were manually entered, and it was a product or a function of the verification team?
A. Yes.
Q. It goes on to say, that, "The verification team is a dedicated team that monitors on a daily basis those orders that the system flags as a suspicious and places on a pend status."
Did you understand that to be the system during this period from 2002 to 2005?

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A. Yes.
Q. And did you understand that the system flagging suspicious orders was synonymous with a pend status?
A. Can you repeat that question?
Q. Sure. It says, "Those orders that the system flags as suspicious and places on a pend status."
So in the system, between 2002 and 2005, an order that was labeled or that was placed on a pend status was a suspicious order?
MR. McDONALD: Object to the form.
THE WITNESS: I wouldn't agree with that.
BY MR. MIGLIORI:
Q. Okay. Would you agree with me that suspicious orders were pended?
A. Suspicious orders were pended. That's correct.
Q. Okay. The verification team was also responsible for verifying

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registration, licensure, et cetera, correct?
A. Correct.
Q. And Kathleen says, "The purpose of this review is to determine if the system is operating in accordance with DEA regulations and whether the thresholds are in line with best industry practices."
So you understood in September of 2005, that was the charge of Buzzeo to determine if Henry Schein was in compliance with DEA regulations and best practices?
A. Correct.
Q. Did you review this in preparation for today?
A. Yes.
Q. So we can go through this quickly. This audit starts out by restating what the Controlled Substances Act requires. We've already talked about that earlier this morning, correct?
A. Yes.

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Q. And it defines suspicious orders including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency. That is what Buzzeo advised you, correct?
A. Correct.
Q. It says, "Henry Schein uses a computerized monitoring system to highlight suspicious controlled substance orders to identify orders of unusual size, frequency, and deviation from normal patterns. Thresholds have been set and reviewed by HSI's staff pharmacist."
That's what the standard operating procedure document says, correct?
A. That's what was reported.
Q. Okay. I want to make sure we're clear, that she's quoting the standard operating procedure document R-03.07, which specifies that, "Henry Schein uses a computerized monitoring

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system to highlight suspicious controlled substance orders and to identify orders of unusual size, frequency and deviation from normal patterns. Thresholds have been set and are reviewed by HSI's staff pharmacist."
That is what the SOP says. Do you see that?
A. Yes.
Q. The findings, however, report out differently. You're aware of that, correct?
MR. McDONALD: Object to form.
THE WITNESS: I'm not aware of that.
BY MR. MIGLIORI:
Q. Let's go to the first finding. The first finding is that, "The Henry Schein system is based solely upon excessive order thresholds. Orders are not highlighted for frequency or deviation from patterns."
Would you agree with me

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that, if true, that is not consistent with the standard operating procedure document referenced above, correct?
MR. McDONALD: Object to the form.
THE WITNESS: I agree that it's not consistent with what it says above. I'm not sure I agree with that specific statement.
BY MR. MIGLIORI:
Q. Okay. So that's why I said if true.
So let's break it down. This first finding of Buzzeo, as reported by Kathleen Malone, is that, "The Henry Schein system is based solely upon excessive order thresholds. Orders are not highlighted for frequency or deviation from patterns."
If Buzzeo is correct, you would agree with me that that is inconsistent with Henry Schein's standard operating procedure document, R-03.07, correct?

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MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. If true?
A. I agree that it's inconsistent with the previous statement.
Q. You don't believe it to be true, based on your recollection?
A. Correct.
Q. All right. "When an order pends, the investigation conducted by the verification team includes the review of order frequency and patterns; however, this review will only occur if the order reaches a threshold limit."
Now, does that refresh your recollection that in 2005, Buzzeo informed you in regulatory affairs that the system didn't highlight deviations in frequency or pattern in and of themselves independently of size?
A. I'm not sure I agree with that statement.
Q. Will you agree with me that

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the independent consultant that you hired is at least in this document reporting to you that your system only flags for deviations in size of orders, not disjunctively for deviations in frequency or pattern? That's what she at least reports to you?
A. The system?
Q. Correct.
A. Correct. The system.
Q. Yeah.
A. But --
Q. And that only when the system kicks out a large -- a deviation in size, does the verification team follow up and actually look at frequency of pattern and frequency?
MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. Deviation of frequency and pattern?
A. I don't agree with that.
Q. That's what she says though,

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correct?
A. That's what she says, but I think it's possible that you still review orders based on frequency and pattern and deviation, could still be done. Just because the system at that particular time was not automated such, doesn't mean that they could not do it manually.
Q. As you sit here today, you don't have an independent recollection that manually, they were proactively looking at frequency and pattern unless triggered by a deviation in size, right? You don't know that that was what was going on?
A. I wouldn't say that it's not going on. I think that there are people in the verifications department that saw orders every day.
Q. Okay.
A. And they -- they had the ability.
See patterns and to see deviations from patterns. Just because

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the system itself at that particular time was not able to do it electronically or in an automated fashion, I don't -- I would not say that the people were not able to do it. They were reviewing orders every day. That's what they did in verifications.
Q. Well, based on her own observations, or Buzzeo's observations, you'll agree with me that Buzzeo recommended to you that a review of the program be conducted to ascertain whether orders can be highlighted for not only unusual size but also for frequency.
Do you see that at least she recommended that your system be changed to capture frequency deviations?
A. Recommended a review of the program, right, right. Program.
Q. Second finding, "There is no formal process in place to review threshold data on a periodic basis, nor is there currently a staff pharmacist available to review the system thresholds

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as stated in the standard operating procedure. The data from the year 2002 study was not available for review."

Do you agree that at least here Buzzeo is identifying that the threshold data was not consistent with the standard operating procedures at Henry Schein, that that's what she is reporting to you?

A. The threshold data was not consistent with -- sorry, could you repeat the last part?

Q. Sure. Buzzeo reports as a second finding to you that "there is no formal process in place to review threshold data on a periodic basis, nor is there currently a staff pharmacist available to review the system thresholds as stated in the standard operating procedure."

Will you agree with me that right here at least, Buzzeo is reporting to you that your system, in 2005, was not consistent with your standard operating

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procedure for review of thresholds?

MR. McDONALD: Objection.

BY MR. MIGLIORI:

Q. That's what she is reporting to you.

MR. McDONALD: Object to the form.

THE WITNESS: No, I disagree with that. I think the way I interpret that, she is saying there is no formal process. She didn't say there was no process. She said there's no formal process in place to review the threshold data on a periodic basis.

So there is a process, it just was not formalized.

BY MR. MIGLIORI:

Q. You would agree with me that standard operating procedures are formalized processes, right?

MR. McDONALD: Object to the form.

THE WITNESS: Standard

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operating procedures are --

BY MR. MIGLIORI:

Q. They are formal processes.

A. Right.

Q. And she is reporting here that you don't have a formal process in place that's consistent with your standard operating procedure. That's what she's reporting. Whether you agree with it is the second question.

She's telling you that, right?

A. No formal process to review the threshold. Right, there's no formal process to review the thresholds.

Q. As is stated in the standard operating procedure, which is what your standard operating procedure says there to be.

MR. McDONALD: Object to the form.

THE WITNESS: Says there to be a review?

BY MR. MIGLIORI:

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Q. A formal process.

MR. McDONALD: Object to the form.

THE WITNESS: I don't know that. It could be -- it could be saying that there's a requirement to review --

BY MR. MIGLIORI:

Q. So you don't accept --

A. Thresholds.

Q. You don't accept her second finding either?

A. I -- no, I'm saying that I don't categorize it as that there was an inconsistency with the standard operating procedure.

I'm answering the question regarding whether there is any inconsistency or there was no process in place you said.

Q. Let me do it a little more differently. Let me make it more plain for you.

Do you agree with the

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finding in September of 2005 that at Henry Schein there is no formal process in place to review the threshold data on a periodic basis, nor is there currently a staff pharmacist available to review the system thresholds as stated in the standard operating procedure?

A. There is no formal process on the staff. I agree with that. No formal.

Q. All right. And she recommended at that time that thresholds be reviewed on a periodic basis to ensure they remain current and applicable. That was recommended to you in this audit, correct?

A. Recommended that thresholds be reviewed on a periodic basis. That's what she recommended.

Q. And so during this review, Buzzeo discussed with Schein conducting a statistical analysis of selected products from Henry Schein product list to determine excessive thresholds. They

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raised the concept of now having a statistical model for suspicious order monitoring, correct?

A. Correct.

Q. The third finding that they found in 2005, it was stated that "approximately 97 percent of Henry Schein's customer base are office-based accounts made up of medical doctors, dentists, midlevel practitioners, and veterinary practitioners. The HIS inventory of available controlled and List I containing drug products is extensive. Currently there is no formal process in place to assess the appropriateness of the customer's medical practice in relation to the drug product being ordered."

Do you agree with that statement, that at Henry Schein, there was no formal process in place to assess the appropriateness of the customer's medical practice in relation to the drug product being ordered in 2005?

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A. In 2005, I would agree. I agree that's what she -- that's what she reported. I can't recall if that was the actual practice -- in 2005 this was? I think we -- the process had begun, or was beginning. Okay.

Q. So do you disagree with Finding Number 3 as well?

A. I'm sorry?

Q. Does that mean that you disagree with Finding Number 3 as well?

A. I would agree with that. That's -- I would agree. I would agree with that.

Q. So she recommended that a formal review be conducted of control drug and List I containing products to ascertain whether there may be products that may be appropriate of all categories of practitioners to order and receive new products added to the HSI inventory. This review should be conducted prior to launching the new product for sale.

She basically recommended a

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formalized process of understanding the practice to the drug, correct?

A. Correct.

Q. You would agree with me that concept is a "know your customer" concept, correct?

A. It's a way of knowing your customer. It is a way.

Q. Okay. Her fourth finding, "Orders that are highlighted as suspicious are all investigated. Those that are cleared from suspicious status are released. Those that are not are canceled. At the end of each month, two reports are submitted to the appropriate field office of the DEA. The first report includes those pended orders that were cleared from suspicious status. The second report reflects those orders that were deemed suspicious and canceled."

Did you understand that that was the practice through 2005 for pended and suspicious orders?

A. Yes.

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Q. Did you understand though in that practice, that she recommended that suspicious orders be reported immediately and not at the end of the month. By reporting them on a monthly basis at the end of the month was inconsistent with the Controlled Substances Act requirements.

MR. McDONALD: Object to the form.

THE WITNESS: In 2005, I don't recall if that was inconsistent with the act.

BY MR. MIGLIORI:

Q. She finds -- she documents here the requirement, "The registrant shall inform the field division office of the administration in this area of suspicious orders when discovered by the registrant."

Her recommendation she writes, "While HSI has been using the current reporting process for several years, it is recommended consideration to

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be given to filing the suspicious order for those orders not released from suspicious status to the DEA immediately."

Do you understand that that was the recommendation then, that reporting them at month's end was not consistent with the requirements of the Controlled Substances Act?

A. That was her recommendation.

Q. Okay. Fifth finding. "When an order pends as suspicious, the order and the customer patterns are reviewed. If it still remains suspicious, a letter is sent to the customer requiring an explanation of the order. A pending order will not be released without a return letter from the customer."

Will you agree with me that the methodology at Schein through September of 2005, and beyond, was, when an order pended, that a letter was sent by first class mail to the doctor or the customer for further information?

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A. Up to 2005. I'm not sure about beyond.

Q. Okay. We'll -- I'll take the beyond out for now.

Do you agree with me through 2005, that was the extent of the -- the due diligence for suspicious orders?

MR. McDONALD: Object to the form. Mischaracterizes the document.

THE WITNESS: The extent of the due diligence?

BY MR. MIGLIORI:

Q. That was the first step of the due diligence process, was to send a letter by first class mail --

A. Right.

Q. -- to the customer for further information.

A. That's -- but that wasn't the extent of it, that was --

Q. I changed it.

A. Okay, okay.

Q. I changed it.

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Do you agree with me --

MR. McDONALD: Why don't you ask the question again, Don?

BY MR. MIGLIORI:

Q. You agree with me that the first step in due diligence with a suspicious order, was to send a letter to the doctor for clarification by first class mail?

MR. McDONALD: Object to the form. Lack of foundation.

THE WITNESS: The first step, I would agree.

BY MR. MIGLIORI:

Q. "When the letter's received and reviewed, if the explanation is found reasonable, the order is released and the letter is retained on file. A notation is made in the system that this letter has been received. This letter is then used to clear additional excessive orders for the same customer."

Were you aware that a cleared order based on that letter, would

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then be used as a basis, that same letter, to clear additional excessive orders for the same customer?
A. Was I aware of that practice?
Q. Yes.
A. No, not...
Q. She recommends that "a careful review of existing letters be conducted each time the same customer exceeds the threshold, even if the same product or product type is ordered.
"If the letter will be relied upon to clear each future excessive order by the customer, a careful review should be made to ensure that the explanation remains viable."
Do you agree that at this point Buzzeo was recommending more follow-up on subsequent or repeat suspensions or pended orders, based on the same letter?
MR. McDONALD: Object to the form.

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THE WITNESS: I think my interpretation, is the customer, if the letter will be relied upon to clear each future excessive order by the customer, a careful review should be made.
That's --
BY MR. MIGLIORI:
Q. And to not just rely on the same letter again, correct?
A. Further review should be made, right.
Q. Okay. Do you recall these recommendations in 2005 from Buzzeo?
A. I don't recall these specific recommendations. There were -- there were -- there were numerous meetings and reviews of the system from this point in 2005 going forward. So there were it was not a -- it was not a -- it was a very dynamic process, where there were several reviews throughout this time period, mid to late 2000s.
Q. My question was simply, do

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you recall this recommendation? Do you recall these recommendations?
A. These recommendations?
Q. Yes.
A. I recall -- generally, I recall these recommendations. Not each individual specific one, but generally, yes, they were recommendations.
Q. And do you recall those findings of inconsistency with standard operating procedures and DEA requirements?
MR. McDONALD: Object to the form.
THE WITNESS: I wouldn't classify it as inconsistent. I would say that they were not perhaps fully automated to the extent that they could easily demonstrate compliance with the DEA regulations.
(Document marked for identification as Exhibit Schein-DiBello-13.)

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BY MR. MIGLIORI:
Q. This is Exhibit 13. We talked about a 2007 letter from Rannazzisi. I just want to ask you quickly. This is a 2000 -- September 27, 2006, letter that Henry Schein produced to us in its files from Joe Rannazzisi the deputy assistant administrator, office of diversion control.
Would you have received this letter if it came to Henry Schein in your role as director of regulatory affairs?
A. I probably would have -- it would have gotten to me.
Q. And you'll see that the purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces?
A. Yes. I see that.
Q. You accept and recall that this is not a new regulation or guidance, but an explanation of the existing

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obligations of distributors?
MR. McDONALD: Object to the form.
THE WITNESS: I wouldn't agree with that. I would say that this is the DEA's attempt at clarifying the responsibilities of distributors and clearly defining or outlining their guidelines.
BY MR. MIGLIORI:
Q. So you agree they use the word "reiterate," correct?
A. They use the word "reiterate."
Q. And you would add "clarifying"?
A. My interpretation, in 2006, reading this now, you know, dated 2006, I don't recall the DEA previously explaining the responsibilities in any communication.
Q. Okay. Well, whether you recall a previous -- you see that they use reiterate. That's just on the face

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of the letter, correct?
A. Correct.
Q. And you've added the word "clarifying." So you would -- you would add the word "clarify" to this, in your interpretation?
A. In my interpretation, based on this document, I don't recall the reiteration process.
Q. I'm just asking about the clarifying part. You would add the word "clarifying"?
A. I -- that's the way I would interpret this.
Q. And on Page 3, in talking about diversion, you'll see that the DEA clarified concepts that suggest behavior of diversion. Do you see that?
A. Yeah.
Q. Ordering excessive quantities of a limited variety of controlled substances, that is an indication of potential diversion, correct?

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A. That's an indication of, okay.
Q. These would be concepts or clarifications or examples of things that distributors should be looking for to know their customer, correct?
A. Correct.
Q. Some of the other things a distributor should seek to look at to see if an order is suspicious is what percentage of the pharmacy's business does dispensing controlled substances constitute. That's how much control to noncontrolled substances. That's one of the things a distributor should look at in its obligation to know its customer, correct?
A. Correct.
Q. Is the pharmacy complying with state laws, not just CSA. That's another "know your customer" inquiry, correct?
A. Correct.
Q. And when the word "pharmacy"

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appears here, in your practice; that is, in the Henry Schein model, that would also apply to doctors, correct, individual customers, not just pharmacies?
MR. McDONALD: Object to the form.
THE WITNESS: I'm not sure I would make that assumption.
BY MR. MIGLIORI:
Q. So you don't look at Henry Schein, what percentage of a doctor's ordering from you is controlled versus noncontrolled?
A. I didn't say that. I said I wouldn't make the assumption that a -- you know, is the pharmacy complying with laws of every state as the same as evaluating a doctor's compliance with the laws of every state.
Q. Would the word "doctor" fit in there for Henry Schein's customers? Is the doctor complying with the laws of every state in which it's dispensing

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controlled substances? Is that an important factor to Henry Schein?
A. Yes. Doctor would be --
Q. I'm sorry.
A. The doctor compliance. But we would verify a doctor's license. A doctor's practice is different than a pharmacy's operation and their compliance. That's my only point.
Q. It doesn't refer to specific laws. It just says complying with the laws of the state. You would expect your doctors to be in compliance with the laws of his or her state?
A. Absolutely.
Q. So these are concepts of know your customer that were shared with you that you would have received in 2006 from the DEA, correct?
A. Correct.
Q. February of 2007. The DEA shared with you, with Henry Schein, another letter.
(Document marked for

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identification as Exhibit Schein-DiBello-14.)
BY MR. MIGLIORI:
Q. This is Exhibit Number 14. February 7, 2007, again signed by Joseph Rannazzisi. That's the assistant administrator, office of diversion control. Again he writes, "The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."
I assume you would add the word "clarify" there as well?
A. Well, reiterate is appropriate now since they are actually reiterating.
Q. Okay.
A. I have no --
Q. Okay.
A. I have no problem with that.
Q. And did you agree that, as of this time, February 7, 2007, that the

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country faced a drug abuse problem?
MR. McDONALD: Object to the form.
THE WITNESS: In 2007, I don't recall the status of the drug abuse problem. But that's -- that's what the DEA stated, that's what they are stating in the letter. But I can't attest to, you know, a drug abuse problem in 2007. I don't recall.
BY MR. MIGLIORI:
Q. It says here, back on it, "As each of you," talking to each of the distributors, "is undoubtedly aware, the abuse, nonmedical use of controlled prescription drugs, is a serious and growing health problem in this country."
Was Henry Schein or were you not aware of that?
MR. McDONALD: Object to the form. He's not here on behalf of Henry Schein. He can talk about what he knows.

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MR. MIGLIORI: That's fine.
BY MR. MIGLIORI:
Q. Were you not aware of that?
A. Was I aware of the drug abuse?
Q. "The, abuse nonmedical use of controlled prescription drugs, is a serious and growing health problem in the country." Were you aware of that?
A. Yes.
Q. And you'll see on the third page that, again, he goes through the different "know your customer" type inquiries that a distributor should consider in satisfying its obligations with respect to detecting suspicious orders and preventing diversion.
Do you see that?
A. Yes.
Q. And so you would have received this kind of information in your role as director of regulatory affairs at Henry Schein in February of 2007, correct?

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A. Yes.
Q. In December of that year, this is the letter that I think you actually referred to in your PowerPoint slide.
This is a little cleaner copy, that we received again from Henry Schein. It says December 27, 2007. Again signed by Joseph Rannazzisi.
(Document marked for identification as Exhibit Schein-DiBello-15.)
BY MR. MIGLIORI:
Q. It's talking about the purpose of the letter is to reiterate responsibilities of controlled substance manufacturers and distributors, to inform DEA of suspicious orders in accordance with the Controlled Substances Act.
And it talks about the obligation to report suspicious orders when discovered by the registrant. Do you see this is a direct reference to the timing of reporting suspicious orders?

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A. Yes.
Q. And you'll agree with me that it also goes on to say that "the regulation specifically states that suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. These criteria are disjunctive and they are not all-inclusive."
You'll see that each of those independently is a suspicious order when detected, according to the DEA in December of 2007.
A. I see that.
Q. And you would have received this kind of information as director of regulatory affairs at Henry Schein in December of 2007?
A. It would have been forwarded to me. Should have been.
(Document marked for identification as Exhibit Schein-DiBello-16.)

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BY MR. MIGLIORI:
Q. Exhibit 16. This is a document produced by Henry Schein to us called Suspicious Monitoring System Specifications Draft.
It again recites the obligations under the Controlled Substances Act. It describes when to investigate. It says, "The regulation also require the registrant to inform the local DEA division of suspicious orders when discovered by the registrant. And registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."
Is that something that you appreciated -- this document, by the way, is -- is January 16, 2008. Is this something that you would have appreciated in January of 2008?
MR. McDONALD: Can I -- where are you getting that from?

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MR. MIGLIORI: Metadata.
THE WITNESS: I would appreciate that, yeah.
BY MR. MIGLIORI:
Q. Okay. And that in your own document, you recite the DEA definition of suspicious orders as being unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. And that these criteria are disjunctive and are not inclusive.
You would agree with me that at this point, Schein appreciates that there is a disjunctive relationship between those three different measures of suspicious order?
MR. McDONALD: Object to the form.
You say your own document. Are you representing that this is his document?
MR. MIGLIORI: Yeah.
MR. McDONALD: It came from his --

THE WITNESS: No.
MR. MIGLIORI: We'll go through it, I'll show you. I'll ask the question differently until we get to that part.
BY MR. MIGLIORI:
Q. Would you agree with me that it was appreciated at Henry Schein that deviations in size, frequency and pattern, were disjunctive, that is, a suspicious order is triggered by any one of those three things?
A. In 2008?
Q. In January of 2008.
A. Yes.
Q. In discussing the new monitoring system to be employed, it says, "The new monitoring system will review orders based on customer market segment, specialty, purchasing patterns, and product active ingredient."
Do you recall that in part of the new SOM project, was to change the monitoring system, and to actually have

it based on those four different criterion?
A. I wouldn't agree that it's a new monitoring system. I think the system was already in place at the time. I would say that the -- I don't know who wrote this document. It's not my document. I don't recall seeing this document. But I don't necessarily agree with that new monitoring.
Q. We'll go back to Exhibit Number 5. Your document sets as September of 2007 the SOM project starting. Do you remember that?
A. Okay. Right. 2000.
Q. January of 2008. This is referring to the new monitoring system will...
Does that refresh your recollection that the SOM project that started at the end of 2007 would include in it a new monitoring system, reviewing orders based on customer market segment, specialty, purchasing patterns, and

products' active ingredients?
A. Well, we can debate whether it's new or enhanced. My point is that it was a monitoring system already in place. Whether these changes or enhancements qualified as a new monitoring system, that's, you know --
Q. So I don't mean to use the word quibble. We're debating whether the word should be new monitoring or the enhanced monitoring system.
But you don't deny that the system that's now being referenced in your timeline, in Exhibit 5, and in this memorandum is a system that is monitoring on new criteria, different criteria?
MR. McDONALD: Object to the form. Mischaracterizes his testimony.
THE WITNESS: I don't -- I don't agree that this is -- you know, I don't agree that this is new criteria. I agree that the system is being automated to --

to -- to be able to readily review the orders for each of these criteria.
Whereas, again, the system was already in existence many years prior to 2008. It may not have been computer -- automated, but it's still -- it was able to review and identify suspicious orders.
BY MR. MIGLIORI:
Q. Well, we just went through -- I don't want to go through them again. But we just went through Buzzeo's findings in 2005, and it wasn't picking up that it needed -- there needed to be a new review of how to check orders for patterns and frequency, not just size. Do you recall that?
A. Yes.
Q. And one of the things this new monitoring system will review is, among other things, purchasing patterns. That is a new way of looking at the

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ordering -- the orders coming into Schein, according to this document.
A. From a systematic approach.
Q. From a systematic approach. And from any approach. That there was, according to Buzzeo in 2005, no independent review of just pattern in the system prior to this change.
A. In the computer system?
Q. Right.
A. In the computer system.
Q. In the computer system?
A. In the computer system.
Q. The system was not picking up changes in pattern or frequency in the computer system.
A. I would agree with that.
Q. And this new system was going to do that.
A. In the computer system.
Q. In the computer system.
And that computer system didn't get implemented in final process until October of 2009, according to your

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chart, correct?
A. Well, there was implementations prior to -- there were steps prior to that.
Q. There were steps. And then in October of 2009 there was a system testing and training completed. So whatever steps there may have been, the training was completed in 2009, in October, correct?
MR. McDONALD: Object to the form.
THE WITNESS: There was training conducted in 2009, right.
BY MR. MIGLIORI:
Q. And --
A. October.
Q. -- then the system completion, the implementation process in that box that you prepared, happened in October of 2009.
It was implemented in October of 2009, this new system we are talking about back here in January of

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2008, correct?
A. Yeah, and there were steps and phases along the way.
Q. You point them all out.
A. Right.
Q. You have the DEA letter we just talked about. There is a finished product normalization that was put together.
A. Right.
Q. There was a Gantt chart that was completed.
A. Right. Statistical --
Q. The suspicious order monitoring statistical approach specs were finalized and submitted.
The -- the questionnaire that we were just talking about, to know your customer, that was implemented for due diligence purposes in June of 2009, right?
A. Customer questionnaire, okay. Right.
Q. This letter we've been

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talking about, that was implemented in June of 2009, the suspicious order monitoring standard operating procedures were revised and finalized in July of 2009, correct?
A. Correct.
Q. And the whole system was implemented with training completed in the verifications team and the regulatory affairs in October of 2009, correct, according to your chart?
A. The complete system.
Q. Right.
A. Altogether.
Q. Right. As director of regulatory affairs, you would have received -- you'll agree with me that this Cegedim Dendrite company was formerly Buzzeo, correct?
A. Yes.
Q. And as director of regulatory affairs in January of 2008, which is when this was dated, you would have received this visit overview,

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correct?
MR. McDONALD: For the record, you're talking about Exhibit 19? 17.
MR. MIGLIORI: 17.
(Document marked for identification as Exhibit Schein-DiBello-17.)
MR. MIGLIORI: Appreciate it.
BY MR. MIGLIORI:
Q. You would have received this?
A. I may have received it, I was not involved in all of the meetings. This could have been a meeting overview of a particular --
Q. I'll save you -- I'll save you some time. Turn to the last page. You're the first person listed as an attendee.
A. Okay. I was an attendee.
Q. Attendee of the opening session?

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A. Of the opening session. Okay, I agree with that.
Q. "Morning session was opened up with general comments about the DEA's changing interpretation of its own regulations and an emphasis on reporting suspicious orders to now include a responsibility for registrants to assure that controlled substances are not being used illegally by customers."
And it says that, "The DEA's communication of December 27th" -- that letter that we just saw -- "was used as a controlling document. And as a result the initial findings were: 1, Schein needs to expand upon its standard operating procedures," that as of January of 2008 Schein standard operating procedures were not sufficient to meet with DEA obligations.
Do you see that?
MR. McDONALD: Object to form. Mischaracterizes the document.

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THE WITNESS: I don't think he said they were insufficient.
He said they --
BY MR. MIGLIORI:
Q. Needed to expand upon them?
A. To expand. Expand.
Q. All right. Expand means to increase?
A. Yes.
Q. They need more?
A. Expand.
Q. All right. We can parse.
"Schein should transition to the new system where only suspicious orders will be reported to the DEA."
So you just report suspicious orders going forward, right?
A. Only suspicious orders will be reported. Okay. I see that.
Q. That, "The precise language of the regulations which requires registrants to track orders of unusual size, orders deviates substantially from a normal pattern, and orders of unusual

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frequency. These specific requirements move from comparing customer purchases to reviewing individual purchasing patterns. Schein will be required to expand its technology to address the fundamental regulatory requirements."
As of January of 2008, if the system wasn't picking up frequency and deviations in patterns, that the system would have to be expanded to do that, correct?
MR. McDONALD: Object to the form.
THE WITNESS: The computer system --
BY MR. MIGLIORI:
Q. Yeah?
A. -- needed to do that, right.
Q. It is the suspicious order monitoring system, correct?
A. Well, they said the technology. I would refer that -- I would interpret that as the computer automated system to address the deviation

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from normal patterns or unusual frequencies.
Q. It says, "Questionable orders are filled and the customer is furnished with a letter requesting an explanation."
So back in January of 2008, questionable orders were filled. Do you recall that being the practice?
A. No.
Q. "And the customer is furnished with a letter requesting an explanation."
Do you recall that through 2008, that was what -- that was what Buzzeo was -- or then Cegedim -- was telling you was Schein's practice?
A. I don't recall this document. And I don't know how they define questionable orders. I don't know what that means, a questionable order.
Q. Do you see that Cegedim's recommendation to Henry Schein in January of 2008 was, "An immediate adjustment

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will be made in Schein's procedures to stop or pend the orders, then investigate to clear prior to shipment"?
Do you see that?
A. I see that.
Q. And do you recall that being put into place immediately in January of 2008?
A. I don't recall in 2008 what they put in place.
(Document marked for identification as Exhibit Schein-DiBello-18.)
BY MR. MIGLIORI:
Q. I'll show you Exhibit 18. Same date, Cegedim issued a report January 28, 2008, issued a report regarding onboarding new customers. This doesn't have an attendee. I can tell you from the Bates information that this is January 28, 2008, the same date as the last document.
It says, "New account issues involving controlled substances. As part

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of Henry Schein's revised suspicious order monitoring system, all new accounts which handle controlled substances will be the subject of a due diligence inquiry."
Do you recall in January of 2008 implementing a due diligence inquiry for all new customers?
A. I don't recall.
Q. The new process includes, "During the diligence inquiry, the new account holder will be interviewed by a Schein staff over the telephone to determine whether the new account appears qualified to handle the controlled substances."
Do you recall that recommendation from Cegedim Dendrite --
MR. McDONALD: Objection.
BY MR. MIGLIORI:
Q. -- in January of 2008?
MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: Where were you

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reading that? Can you point that out?
BY MR. MIGLIORI:
Q. The second sentence.
A. "During the diligence inquiry, the new account holder..."
MR. McDONALD: Same objection. Lack of foundation.
THE WITNESS: I don't recall that.
BY MR. MIGLIORI:
Q. Do you know whether that was ever implemented? Do you know that whether new clients were all subject now to due diligence at the intake, beginning with this new suspicious order monitoring program?
MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: I don't recall.
BY MR. MIGLIORI:
Q. Do you recall Dendrite saying that in that first interview that

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information to be acquired may include obvious information like licenses and registrations, personal information such as dates of birth and social security numbers, and what controlled substances the customer anticipates ordering and quantities? Do you recall that recommendation from Cegedim?

MR. McDONALD: Object to the form. Lack of foundation.

THE WITNESS: I don't agree with that. Licenses and registrations were always part of the system, were always required. That's -- that's a no brainer.

BY MR. MIGLIORI:

Q. I think they refer to that as obvious information.

A. Information to be acquired during the interview may --

Q. May.

A. -- include.

Q. May include.

A. Right.

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Q. Then they say obvious information, license and registration. And then they ask for more specific information. Do you recall that?

A. I don't recall this. But I was clarifying that licenses and registrations were always maintained. I don't know why that would have been a recommendation or as -- information to be acquired. That's --

Q. I think what's new here is doing it over the phone in an interview, not the information. Isn't that what it says?

A. Why do it over the phone?

MR. McDONALD: Hang on. Hang on.

Object to the form.

BY MR. MIGLIORI:

Q. I'll read it again. "During the due diligence inquiry, the new account holder will be interviewed by Schein staff over the telephone to determine whether the new account appears

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to be qualified to handle the controlled substances."

Do you see that?

MR. McDONALD: Are you simply just asking him if that's in the document?

MR. MIGLIORI: Well, right now I am, because he just asked why would it be over the phone. So I had to repeat it to him.

MR. McDONALD: Well, you also haven't established that regulatory had anything to do with this due diligence inquiry.

MR. MIGLIORI: I established that regulatory was the one that facilitated the relationship with this company.

BY MR. MIGLIORI:

Q. Do you recall this process being recommended in January of 2008 as part of the onboarding of new clients, that Schein picked up the phone and interview all new clients and ask for

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things, including obvious things, like licenses and registration, but more detailed information, like birth dates, social security numbers, and how they anticipate ordering controlled substances?

MR. McDONALD: Object to form.

BY MR. MIGLIORI:

Q. Do you recall that?

MR. McDONALD: Object to form.

THE WITNESS: I don't recall it, and I disagree with it, because licenses and registrations were maintained and verified electronically. That's why I disagreed with this statement, just because there are certain documents that, why would we ask over the phone when we had hard copies.

BY MR. MIGLIORI:

Q. Fine.

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A. So --
Q. What about the rest of it? This is a new customer you're talking about, during an interviewing. You're saying that you already have the hard copies before you --
A. The verification --
Q. -- took on new customers?
A. The verification group, to set up an account, step one was DEA license, DEA registration, State Board of Pharmacy license. That was standard operating procedure.
Q. Okay.
A. Customer account information, Dr. John Smith.
Q. Did they do it by phone?
A. Did they do it by phone?
Q. Right.
A. That was a verification function. I don't know how they did it. But they -- in order to set up an account, they had basic information that they required from the customer. And

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that basic information is the customer account, which are also publicly available on the board of -- boards of pharmacy's websites as well as DEA. Why would we -- that makes no sense.
Q. So your consultant makes no sense here?
MR. McDONALD: Object to the form.
THE WITNESS: At this point I disagree with this -- why we have to do that verbally again over the phone when it was standard operating procedure. I don't know.
BY MR. MIGLIORI:
Q. Do -- do you see that they say obvious information and then go on to other bits of information?
A. Yes. The other bits are also obvious.
Q. It's obvious to look at what the prescribing, anticipated prescribing, or ordering would be?

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A. That's -- that's not obvious. I would -- I would agree with that, that's not obvious.
Q. And is that something that you did?
MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. In January of 2008. Is that something that you agreed to take on at the recommendation of the company that you paid to consult on this issue?
MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: I -- I don't recall what they -- what they did in 2008.
BY MR. MIGLIORI:
Q. After the interview, they recommend that the customer be provided with a document with information pertaining to controlled substances which addresses basic legal issues such as legitimate medical use.

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Did Henry Schein ever take that recommendation and implement it for new customers?
MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: That was their recommendation and that would have been implemented.
BY MR. MIGLIORI:
Q. Did you -- did you implement it?
A. We would not -- regulatory would not have implemented. That is a verification function.
Q. Do you know if Henry Schein implemented it?
MR. McDONALD: He's not here on behalf of Henry Schein.
BY MR. MIGLIORI:
Q. It's okay if you don't know. I'm asking whether you as director of regulatory affairs know whether this was implemented.
A. I don't recall.

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Q. Do you know if a signed document from the client acknowledging receipt of that information was required?
MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: I don't recall.
BY MR. MIGLIORI:
Q. What about this, "A background investigation should be conducted to determine whether there are convictions or regulatory actions in the clients' past that may affect their suitability for ordering controlled substances."
Cegedim recommended that in January of 2008. Do you know if your company or if regulatory or verifications ever implemented a "know your customer" inquiry about prior convictions that may affect the suitability for ordering controlled substances of a new client?
A. Convictions, I don't recall that. I don't recall.

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Q. Is that a good recommendation?
MR. McDONALD: Object to the form.
THE WITNESS: Do I think it's a good recommendation?
BY MR. MIGLIORI:
Q. Yeah. Do you think that's a good "know your customer" practice, as director of regulatory affairs for Henry Schein, to do a criminal background check to see if that may impact whether or not a new doctor would be an appropriate customer for controlled substances?
A. I would have to -- I would have to evaluate that in light of the industry practice and at that time what -- what would be acceptable and not. And I'm not even sure that -- I'm not even sure how we would be able to access a doctor's criminal convictions. I don't even know how a doctor would still be able to maintain their license to practice medicine if they were convicted

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felons or -- I'm not sure how they would even be able to maintain their -- their basic medical license.
Q. Do you remember in the DEA letter from Joe Rannazzisi, where the DEA tells you that the mere maintenance of a DEA registration is not due diligence?
Do you remember hearing that from Joe Rannazzisi or reading that? Do you recall that?
A. I'm sorry?
Q. Do you recall that?
A. Do I recall reading that?
Q. Yeah.
A. I don't recall.
Q. Okay. Would you agree with me that as the director of regulatory affairs for Henry Schein, that it would be insufficient if asked by the verifications team to just go and look to see if a doctor had a valid DEA registration for purposes of performing due diligence under the Controlled Substances Act?

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MR. McDONALD: Object to the form.
THE WITNESS: The DEA -- the verifications group were looking at doctors' licenses, including the DEA registration, so they wouldn't -- they would not just look at the DEA registration. They would look at their other licenses.
Their board of pharmacy license, their Department of Health depending on the state that they were in.
BY MR. MIGLIORI:
Q. My question is a little more simple.
Would you agree with me that it is insufficient to rely merely on the fact that a doctor has a DEA registration as adequate due diligence when investigating a suspicious order?
MR. McDONALD: Object to the form.

THE WITNESS: I would agree.
BY MR. MIGLIORI:
Q. Would you agree with me that in his February 7, 2007, letter to you that you received, Joe Rannazzisi expressly said to you, that is to Henry Schein --
MR. McDONALD: Why don't you hang on and let him find the letter so he can read along with you?
MR. MIGLIORI: Or you can look on the screen, either way.
MR. McDONALD: Well, that's -- I'll tell you it's difficult to see.
Do you know which exhibit it is?
MR. MIGLIORI: I'm guessing it's somewhere around 15 or 17.
MR. McDONALD: Which one -- which one?
MR. MIGLIORI: The February 2 letter?

MR. McDONALD: February 7 letter?
MR. MIGLIORI: Yes. February. Only one in February.
MR. McDONALD: 14.
MR. MIGLIORI: 14.
MR. McDONALD: Exhibit 14, you have it.
THE WITNESS: Okay. February 7th. Okay. Page 2?
BY MR. MIGLIORI:
Q. Yes. Second to the last paragraph.
"In a similar vein, given the requirement under Section 823(E) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to suspicious circumstances."
Do you remember that message from the DEA in February of 2007?
A. I recall the -- when you say

the message, the letter, yeah. But I just want to clarify something.
In the context of suspicious orders, that's a different process as opposed to account setup. That's the distinction. So when we are talking about suspicious orders, there is a -- there's a review that obviously if the order was suspicious, we're going to examine it carefully.
Q. Which is called due diligence, correct?
A. Well, it's -- it's a review of the order, that particular order, which would include the doctors' status.
Q. The review of the doctors' status, by Henry Schein's own words, is due diligence, correct?
A. You can -- you can -- well, due diligence could also mean when -- when an account is set up.
Q. Exactly.
A. And we conduct -- we conduct an assessment, you know, of the -- of the

doctor's account, an onsite visit, a questionnaire.
So due diligence, at what point in the process are you referring to? There's different levels of due diligence.
Q. I completely agree.
A. Okay.
Q. But my question was way more fundamental.
A. Okay.
Q. Henry Schein, when it investigates whether an order is suspicious, conducts what is called due diligence and the files that they maintain are called due diligence files, correct?
A. I don't recall a particular, you know, file on a doctor. You know, again, that function was a verification function when an order was deemed suspicious.
Due diligence, from my perspective, from the regulatory

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perspective, would include an onsite assessment.
Q. It doesn't have to include an onsite assessment, does it?
A. It doesn't have to, but it --
Q. In fact, 90 percent -- no, I shouldn't -- I can't give you a percentage.
Of the due diligence files that were produced to us in this case, the vast majority of them had no site visit?
A. At what point in time are you referring to?
Q. Whatever was given to me, from 2009 through 2016, I think is what I got.
A. Okay. Well, again, the timeline, right, depending on where we were on the timeline, is when the onsite assessments were implemented. So if we're talking about 2002 to 2007, yeah, you're not going to find --

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Q. Okay. Let's get back down to earth.
In front of us is a document where a system was implemented or was suggested by Cegedim Dendrite for new accounts to perform due diligence inquiries. Do you see that?
A. Yes.
Q. They recommended a phone call as part of the new due diligence inquiry, correct?
A. That's what they recommended.
Q. They also recommended a follow-up with a document talking about legal issues related to legitimate medical use, correct?
A. Okay.
Q. And they recommended that there be a receipt so that customers -- new customers would acknowledge receiving such -- basically, the document, correct?
A. Okay.
Q. And then they say that, "A

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background investigation should be conducted to determine whether there are convictions or regulatory actions in the client's past that may affect their suitability for ordering controlled substances."
Do you see that, first of all?
A. I see that.
Q. Do you know if Henry Schein ever implemented that process for new customers in the new customer due diligence inquiry?
A. I don't know.
Q. Would you agree with me that a doctor who had prior convictions for drug trafficking who wants to become a new customer of Henry Schein would have to explain to Henry Schein the prior conviction? Would you agree that that would be an important due diligence inquiry for Henry Schein?
MR. McDONALD: Object to the form.

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THE WITNESS: I agree that it would be. But I do not agree that it would ever get to that point because the doctor's license, his license to practice medicine would be revoked or should be revoked.
I mean, I'm not --
BY MR. MIGLIORI:
Q. And let's say it wasn't. Based on what we just saw with Dr. Rannazzisi's -- Joe Rannazzisi's letter.
A. Joe Rannazzisi was talking about the DEA registration.
Q. Which a doctor has for controlled substances?
A. In addition to -- in addition to his -- his State Board of Pharmacy license, which, by the way, his DEA registration is contingent upon his license, his State Board.
Q. Right.
A. Okay. So if -- again, I'm

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not --
Q. I'm going to give you a fact pattern. Because I think right now we're enjoying going afield of each other, and I want to just focus this, okay. I take full responsibility for it.
MR. McDONALD: Just listen to his question. Okay.
BY MR. MIGLIORI:
Q. A doctor who has a prior conviction for drug trafficking who has his license revoked and his DEA registration suspended and reinstated seeks to become a new customer of Henry Schein.
Does Henry Schein, as of 2009, under this new system, do an inquiry of that new customer, of whether or not he or she has had prior convictions for drug-related offenses?
MR. McDONALD: Under your hypothetical, the license has been revoked? That's what you said?
MR. MIGLIORI: And then I

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said -- and then reinstated.
MR. McDONALD: You said his DEA registration has been suspended and reinstated. So both have been revoked and both have been reinstated?
BY MR. MIGLIORI:
Q. His license revoked and DEA registration suspended and reinstated, referring to both.
Let's say a doctor is in fact convicted of drug trafficking.
A. Okay, okay.
Q. And his licenses are revoked --
A. Revoked.
Q. -- and reinstated.
A. And then reinstated. Okay.
Q. In 2009, does Henry Schein inquire of that doctor of his or her criminal convictions that may be related or informative of whether or not that doctor should be ordering controlled substances?

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MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: So that would be a verification function. And when they are setting up the account, and I don't want to guess --
MR. McDONALD: Don't guess. You're not here to guess.
THE WITNESS: I'm not going to guess what their --
MR. McDONALD: If you know, tell him. If you don't, tell him that you don't know.
THE WITNESS: I don't know what their practice would be in that hypothetical.
BY MR. MIGLIORI:
Q. All right. In this document in front of us, Exhibit Number 19, it says, that background investigations should be conducted in that situation. And I'm asking you whether or not they were, whether or not regulatory and

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verifications implemented this change.
MR. McDONALD: Object to the form. Mischaracterizes the document.
THE WITNESS: I don't know.
MR. McDONALD: Objection, lack of foundation.
BY MR. MIGLIORI:
Q. It says, "A background investigation should be conducted." Do you know if they ever were, from January of 2008 forward?
A. Well, background investigations were conducted on doctors, on accounts.
Q. For new customers?
A. I don't recall for new customers.
Q. Was it a good idea?
MR. McDONALD: Object to the form.
THE WITNESS: Do I think it's a good idea?
BY MR. MIGLIORI:

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Q. Yeah.
A. Absolutely.
Q. Would you have concern as director of regulatory affairs for a doctor who does have a drug trafficking past wanting to buy an order of controlled substances from Henry Schein?
A. You're asking me would I have a concern if a doctor had a drug trafficking violation?
Q. Conviction.
A. Conviction?
Q. Yes.
A. Wanted to buy pharmaceutical, controlled substances?
Q. Yes.
A. That would be concern.
Q. If verifications escalated that new customer inquiry to you and to Sergio Tejeda, that we have a customer here that wants to buy controlled substances from us, but in fact it turns out that over a decade ago, that doctor was convicted of drug trafficking, that

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would be something concerning to you, correct?
MR. McDONALD: Object to the form. Improper hypothetical.
BY MR. MIGLIORI:
Q. As director of regulatory affairs at the time?
A. I would be concerned.
Q. But whether or not this was actually implemented going forward, you just -- you just don't know as you sit here today, is that a fair statement?
A. I don't know what verification implemented on all these -- you know, there are lots of enhancements that were made.
MR. McDONALD: Let's take a break. We've been going for a while.
MR. MIGLIORI: Sure.
THE VIDEOGRAPHER: All right. Remove your microphones. The time is 3:10 p.m. Off the record.

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(Short break.)
THE VIDEOGRAPHER: We are back on the record. The time is 3:29 p.m.
(Document marked for identification as Exhibit Schein-DiBello-19.)
BY MR. MIGLIORI:
Q. Let me show you Exhibit Number 19. It's the same time frame. It's now February of 2008. It's an e-mail exchange between you and Sergio.
And again, if we start at the end, there is a reference to Sergio summarizing the HDMA meeting from last week dated February 6, 2008. And the covering e-mail that I'm going to ask you about is from Sergio to you February 6, 2008.
It says, "Mike, please take a look at my response to Jim before I send it."
So Mike writes: -- I'm sorry, Sergio writes, "As you know, this

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was a meeting facilitated by the HDMA to discuss a proposal to the DEA on best practices for distribution of controlled drugs which will be accepted and observed industrywide. The goal is to come up with something that will satisfy DEA officials to get their buying into that industry is addressing their concerns and no additional actions against the wholesalers is necessary.
"The main issues that raised a concern and would have a substantial affect on our operations were:"
And Number 1, it says, "Due diligence on new accounts. The proposal was that the companies will need to perform an onsite review of every new account before they could be opened for controlled substances. Obviously most of the companies represented in the meeting have a different business model than HSI. Most of them service pharmacies and retailers or regionals which do not do much volume. We argued that the amount

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of new accounts Henry Schein opens daily, it will be virtually impossible to visit all of them and proposed to have different levels of review for different types of customers with office-based practitioners being in the low risk end and, therefore, subject to lesser level of review.

"We also discussed other alternatives like self-certification and third-party certification."

Do you recall this exchange with Sergio?

A. I don't recall this particular e-mail.

Q. Do you recall Henry Schein's concern about the impracticality of visiting with all new customers based on the number of new accounts Henry Schein opens daily?

A. I recall that it would be a challenge. It would be a challenge to conduct an onsite.

Q. Do you recall whether or not

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Henry Schein adopted any industrywide recommendation to do onsite visits of new customers?

A. No, I don't recall Henry Schein adopting -- industrywide? No.

Q. Industrywide recommendations.

A. Recommendations, yeah.

Q. Did -- did Henry Schein visit with each new customer?

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

Q. After in 2008?

A. I don't know. Every customer, I don't know.

Q. You don't know, or no?

A. I don't know.

Q. Okay. And you don't know whether they even made phone calls for every customer, correct?

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

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Q. Based on the last recommendation we reviewed?

A. That was not a regulatory function.

Q. The question was, do you recall if they did do that?

A. I don't recall.

Q. Okay. Do you know if Henry Schein adopted a self-certification process as an alternative to visiting with new customers?

A. I don't know.

Q. Do you recall if Henry Schein adopted a third-party certification process for new customers?

A. We used Buzzeo and other -- you know, we used -- I'm not sure what third-party certification is. But we -- we used consultants to conduct onsite audits.

Q. For new customers?

A. For all customers.

Q. Including new customers?

A. Including new.

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Q. Do you know when that started?

A. I don't recall the time period, but I know we used Buzzeo and -- and others.

Q. Okay. There's a reference in the third paragraph that these changes will represent additional costs and resources to the distributors.

Do you recall having that concern in 2008, that additional new customer due diligence would be expensive or take up a lot of human resources?

MR. McDONALD: Object to the form.

THE WITNESS: I don't -- I don't recall that, being any additional cost.

(Document marked for identification as Exhibit Schein-DiBello-20.)

BY MR. MIGLIORI:

Q. I'll show you Exhibit 20. I'm not going to go too deeply into this

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one.
We made reference to the HDMA and a guidance that they put out in 2008. Do you recall the 2008 HDMA guidance on suspicious orders? Suspicious order monitoring and compliance with DEA?
A. Vaguely recall.
Q. And at this time, Henry Schein is an active member of HDMA, correct?
A. Henry Schein is a member of HDMA.
Q. And you attended HDMA conferences yourself?
A. Yes, I did.
Q. And you, in part, relied on HDMA to learn about DEA compliance, correct? Isn't that one of the examples you gave me earlier?
A. We attended conferences and we -- we attended other conferences. Not just HDMA.
We -- we relied on some of

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their guidances. They were guidances.
Q. I'm just simply asking you, was this one of the examples of the trade associations where you got on-the-job training for DEA compliance?
A. This was one example. Yes.
Q. Okay. And on the first page of this guidance, Exhibit Number 20, it says that "these industry compliance guidelines are consistent with and further extend the distributors' track record of supporting and implementing initiatives designed to improve safety, security, and integrity of" -- "of medicine supply. They have been prepared in recognition of a growing problem of misuse and diversion of controlled substances, and the critical role of each member of the supply chain in helping to enhance security."
Did you agree with that statement?
A. Did I agree with that statement in 2000 -- when was this

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issued?
Q. 2008. The actual date of it is November 13, 2008.
A. The -- I don't agree with the statement in its entirety.
The -- HDMA was comprised of many distribution companies, small, large, regionals, so I think they tried to -- tried to unify the industry best practices. But I don't know if they -- if these guidelines were consistent with all of their membership.
Q. Okay. Was there something about these guidelines that Henry Schein took particular issue with, that you can recall?
A. Not particularly. Nothing jumps out at me, but...
Q. Do you agree with the statement that -- that these guidelines were prepared in recognition of a growing problem of misuse and diversion of controlled substances and the critical role of each member of the supply chain

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in helping to enhance security?
A. Yes.
Q. Okay. The next sentence, it says, "At the center of the sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."
Do you agree that distributors are uniquely situated to perform the due diligence in order to prevent diversion?
A. I wouldn't say -- they're part of the supply chain, but I don't know if I would use the word "uniquely." Uniquely situated. They are just another -- you know, distributor is a part of the supply chain.
Q. So as director of regulatory affairs at Henry Schein during this period of time through 2012, you didn't feel that Henry Schein had a unique position in order to prevent diversion

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and misuse and abuse of opioids?
A. We had a position. We had, as a member of the supply chain, everyone had a role, a very important role. I'm not sure that I would say one was more important or one was more unique or different -- different situated -- okay.
Q. Do you accept the concept?
A. It's okay.
Q. Do you agree that due diligence can provide a greater level of assurance that those who purchase controlled substances from distributors intend to dispense them for legally acceptable purposes? That that is the goal of due diligence?
A. Yes.
Q. I'm not going to go through the whole document. But if you look at the Page 4 of 15. There's a section titled "Know Your Customer Due Diligence."
A. Okay.
Q. And do you see that whole

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first section talks about opening new accounts?
A. Okay.
Q. The first suggestion of a guidance from the HDMA, the trade association to the distributors, is the distributor should obtain background information on the customer and the customer's business. Do you accept that as an industry-wide best practice, that the distributor should obtain background information on the customer and the customer's business?
A. Okay. I accept that.
Q. Yes?
A. Yes.
Q. Review the information carefully and, where appropriate, verify the information, do you agree that that's a best practice for a distributor?
A. Okay.
Q. Is okay yes?
A. Yes.
Q. Okay. And three, a

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distributor should independently investigate the potential customer. Do you agree that's the best practice for a distributor to independently investigate the potential customer of controlled substances?
A. In 2008?
Q. Yeah.
A. Yes. Yes.
Q. "To help ensure that the industry compliance guidelines remain robust and adaptable, the 'know your customer' due diligence phase also describes additional recommendations and documentation containing further suggestions for managing the distributor's procedures."
It goes on to specifically reference different types of information to gather. Do you know if, first of all, you received these guidances in or around November of 2008, you personally in regulatory affairs?
A. In around November of 2008,

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yeah, yes. I agree somewhat.
Q. Do you recall implementing any of these best practices as recommended by the HDMA into the Henry Schein system?
A. I don't recall specifically which -- you know, which best practices or any that we implemented.
Q. Do you know whether any onboarding of new client standard operating procedures were changed as a result of this guidance?
A. I don't recall.
Q. But this is a guidance that you would have perceived and would have had in your possession --
A. Yes.
Q. -- at or around the time that it was made, correct?
A. Yes.
(Document marked for identification as Exhibit Schein-DiBello-21.)
BY MR. MIGLIORI:

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Q. Exhibit 21 is a confidential interoffice memorandum from Brian -- how do you pronounce his last name?
A. Loiacono.
Q. Loiacono and Craig Schiavo, copying you and Sergio. Did you review this document in preparation for today?
A. No.
Q. This is a confidential interoffice memorandum regarding pain management clinics and recommendations. Do you recall around May of 2009 doing -- regulatory affairs conducting due diligence audits on customers of Henry Schein?
A. I don't recall specifically -- May 2009 doesn't stand out, but we conducted many audits throughout that time period.
Q. Do you recall Physician's Choice Dispensing Services, PCDS, the pain management clinic?
A. Not specifically.
Q. The memorandum says, "While

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conducting our assessments of these facilities we found that most met the minimum DEA requirements, i.e., security and recordkeeping; however, compliance with the minimal DEA requirements does not necessarily convey the legitimacy of the pain clinic. The issues listed below pose serious concerns in regards to shipping controlled substances to pain clinics."
Do you recall doing a deeper dive on this particular customer beyond what they're calling here the minimum DEA requirements?
A. I don't recall.
Q. In investigating these clinics, it was found that a lot of these were cash-only businesses.
Do you see that?
A. Yes. Cash only. I see that.
Q. There was also a finding that treatment of a large percentage of the patients were out of state.

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Do you see that finding?
A. Yes.
Q. Do you see that for this particular group of clinics, there was a large percentage of orders of controlled substances over noncontrolled substances?
A. Yes.
Q. Do you agree with me that's one of your "know your customer" inquiries that had been recommended by Buzzeo and by the HDMA?
A. Yes.
Q. The other inquiry was a quantity of patients that actually see a doctor. "In some cases, we witnessed lines outside of the facility well before office hours."
Do you agree that waiting lines in front of doctors or pharmacies is an indication of potential diversion?
A. Could be.
Q. And that's one of the recommendations for inquiry and due diligence by Buzzeo and HDMA?

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MR. McDONALD: Object to the form.
THE WITNESS: That's one of the recommendations --
BY MR. MIGLIORI:
Q. Due diligence inquiry.
A. To look at the --
Q. Whether or not there are patients in waiting lines and -- before opening. Do you ever recall that red flag being identified as a point of inquiry?
A. I don't recall that as a red flag, but mm-hmm.
Q. And do you recall that based on those findings that regulatory affairs, your department, and Ron Buzzeo recommended cutting off PCDS as a client?
MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. As a customer?
A. I don't recall this specific account. There were many accounts. I

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don't recall it.
Q. You would agree with me that at least on the face of this document, these aren't triggered by thresholds, size of an order, frequency of pattern, correct? That these are principles of know your customer, correct?
A. Correct.
Q. And that a customer could be a customer to whom you should not be selling controlled substances just based on concepts of knowing your customer due diligence, correct?
MR. McDONALD: Object to the form.
THE WITNESS: Can you repeat that question?
BY MR. MIGLIORI:
Q. Sure. You don't need a variation in size, frequency, or pattern of order in order for a customer to be an inappropriate customer for controlled substances after doing or performing due diligence and this kind of inquiry,

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correct?
A. I agree.
Q. And that the obligation to know your customer is an ongoing obligation; that is, it's not only triggered by a deviation of order in size, frequency or pattern, correct?
A. Correct.
Q. It starts with onboarding the customer and then continues through any orders of controlled substances, correct?
MR. McDONALD: Object to the form.
THE WITNESS: Correct.
(Document marked for identification as Exhibit Schein-DiBello-22.)
BY MR. MIGLIORI:
Q. Let me show you Exhibit Number 22. This is another Cegedim Dendrite report. This one is dated 11/2/2009. And based on, again, the timeline that you created, this would be

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right after the implementation -- full implementation of the SOM project, correct? If we look at the SOM process timeline in Exhibit Number 5, correct?
MR. McDONALD: I'm sorry. You are representing to the witness that this document is dated November 2nd, 2009?
MR. MIGLIORI: Yes.
MR. McDONALD: I don't understand how that's possible. On the second page, it refers to a meeting that's dated December 16, 2009.
MR. MIGLIORI: Okay. I appreciate that. So it's after that. I don't know where the metadata came from then. But we can at least put now, instead of November 2nd, it's after December 16, 2009.
Thank you.
BY MR. MIGLIORI:
Q. Do you see this report?

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A. Yes.
Q. By Cegedim?
A. I see it.
Q. Okay. And again, that is the -- it's still after the implementation of the new SOM procedures, correct, or the implementation of the SOM project started in 2007, correct?
A. It's after 2007?
Q. No. It's after the implementation of that project in 2009.
A. After the implementation in 2009.
Q. And in this particular suspicious order monitoring procedural review, it says, "The guidance provided directly through the regulations was further amplified in correspondence delivered by the DEA in December of 2007."
We referred specifically to that letter, right? You remember that?
A. The Rannazzisi letter?
Q. Yes.

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A. Yes.
Q. "And in correspondence, the DEA established expectations that registrants will actively investigate prospective customers and aggressively investigate orders pending to filling them."
Do you see that?
A. Yes.
Q. All right. If you go to the conclusions on Page 4, in referring to the recommendations of Buzzeo, it says, "Some of the original recommendations are still open, including the development of procedures to govern and control access codes and the validation of a computer system."
So as of this date, which is, as counsel points out, after December of 2009, there were still some access codes and validations that had not been completed. Do you see that?
A. I see that.
Q. The third bullet point says,

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"New accounts are opened without sufficient due diligence investigations/inquiries. For the most part, new accounts are opened based upon a verification of the customer's DEA number, which is not considered adequate by the DEA."
Do you recall being told sometime after December of 2009 that new accounts were not being opened with sufficient due diligence?
A. No.
Q. "Correspondence regarding the prospective customer's previous history of using controlled substances, office practice rules, and general practice expectations should be completed prior to opening the new account."
Were you aware that those were not being done before opening a new account?
A. I don't recall.
Q. A compliance agreement form should be developed and included in the

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new account opening process.
Will you agree with me that at least as of the end of 2009, there was no compliance agreement as part of the due diligence process for new customers?
A. I don't know what a compliance agreement form is.
Q. Okay.
A. I've never seen this document. And there were meetings that were ongoing throughout the entire and -- and post-implementation process.
Q. Okay.
A. So it was -- again, it was a dynamic evolutionary process that was constantly being enhanced and improved.
Q. You would agree with me that this enhancement and improvement was in coordination with the regulatory affairs department and verifications?
A. It was -- regulatory's role was to work with other departments that would -- that would implement certain enhancements, such as the verifications

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group and the IT group. And so there were multiple parties working on these enhancements.
Q. Okay. My question was simply, you'll agree with me that two of those parties were verifications and your department, regulatory affairs, correct?
A. Two of those departments, yes.
Q. All right. It also says here that "the use of Med Pro inquiry should be expanded for all controlled substance accounts and not just for the limited number of states that require this background check."
Were you familiar with the Med Pro inquiry system?
A. No.
Q. All right. We'll move on.
"Henry Schein has conducted some onsite investigations for prospective customers; however, the criteria for level of due diligence has not been documented in any standard

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operating procedure or memorandum."
Is it your recollection that as of the end of 2009, Henry Schein had no standard operating procedure for when and how to do onsite investigation for prospective customers?
MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: I don't recall the date of the standard operating procedure.
BY MR. MIGLIORI:
Q. Okay. At least according to this document, as of December of 2009, Henry Schein, according to this Dendrite report, did not have a standard operating procedure for onsite investigations of prospective customers. That's what the document says, correct?
A. That's what the document says.
Q. Then another observation was that "at the end of 2009, lower level staff is actively involved in clearing

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pended orders. Pended orders should be cleared by a management official."
Was that true that at the end of 2009, low level staff at -- in the verifications department was still actively clearing pended orders without management involvement?
MR. McDONALD: Object to form. Lack of foundation.
THE WITNESS: I don't -- I don't know what level of management reviewed verification pended orders. That's verification.
BY MR. MIGLIORI:
Q. Cegedim states on the bottom of the conclusions and recommendations that "Henry Schein has clearly invested a great deal of time and energy in developing an adequate SOM system. However, the responsibilities of the customer service department, the verifications department, and the regulatory department appear to be poorly

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defined and reliant to some extent upon the judgment of individual employees regarding what types of situations should be referred to management for approval or forwarded to regulatory for investigation."
Was that the state of the interrelationship between those two departments at the end of 2009, that the relationships were poorly defined as stated here?
A. This is the first time I'm seeing this document, and I -- I don't agree with that comment.
Q. Okay. So you don't recall being told by Cegedim, a consultant that you hired to review your suspicious order monitoring program, that the three departments, customer service, verifications, and regulatory affairs, had poorly defined roles in the suspicious order monitoring system? You don't recall being told that?
A. No.

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Q. You'll agree with me that that's what they are representing here in this document?
A. That's what the document says.
Q. Okay. And you see under qualifications and disclaimers that Cegedim is saying, "Implementation of these recommendations does not guarantee that the DEA would not find any violations. The recommendations must be considered with this in mind."
So, to your knowledge, as you sit here today, do you know if any of these recommendations were, in fact, implemented?
A. I don't recall specific recommendations that were implemented or not.
(Document marked for identification as Exhibit Schein-DiBello-23.)
BY MR. MIGLIORI:
Q. I'll show you Exhibit

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Number 23.
This is an e-mail chain.
The top e-mail is from Craig Schiavo dated February 10, 2011, addressed to you, and it refers to the SOM procedures. And then it says, "Here is the PDF of the review and release procedure in case you couldn't open the Visio version."
Do you recall new suspicious order monitoring procedures being implemented that had a change in the review and release procedure?
A. Had a change in the review and release procedure?
Q. Yep.
A. I don't recall specifically that.
Q. If you look at the -- the lower e-mail on the first page.
A. Okay.
Q. Craig Schiavo writes to you and copies Sergio and says, "Mike, attached are the new suspicious order monitoring procedures we have

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implemented. You may not be able to open one of the review and release procedures if you don't have Visio. If not, please let me know and I will send you a PDF."
And then it talks about the controlled substance monitoring and reporting procedure. Review and release procedure. New account setup procedure.
Do you recall receiving this information in February of 2011 relative to the new SOM procedures being implemented?
A. No.
Q. If you turn to the next page. There is a diagram of the review and release procedure. It talks about a pended order at the top of the diagram. Do you see that?
A. Yes.
Q. And then the shipment once pended was placed on hold. Was that the procedure in 2011? It was pended, the shipment was held up?
A. I believe that was the

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procedure.
Q. Once pended, the preliminary review happened at the verifications level, correct?
A. Verification, review, right.
Q. And that constituted a website search, a Google search, a DEA website search, a licensure search. Those are some examples of what happened at that first level review, correct?
A. Correct.
Q. That was not necessarily done by management, that was done by staff, correct?
MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: I don't recall who in verification did that.
BY MR. MIGLIORI:
Q. Okay.
A. Of what their titles were.
Q. If the order was released, it would be deemed legitimate and sent, if the order was okayed after that

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internet search, correct?
A. That was the decision block there.
Q. If it wasn't cleared there, verification required a justification letter and questionnaire from the customer. So a letter would be sent out to the customer for justification of the order, correct?
A. That's what it says.
Q. Is that what you recall too?
A. I don't recall the specific verification review process. But that's -- that's what it says.
Q. According to this, the first step was going on the internet and do a search on the internet. The second step would be to send a letter first class mail to the customer for a written response. That's what the blocks -- that's the current flowchart, right?
MR. McDONALD: Object to form. Nowhere on there does it say internet.

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MR. MIGLIORI: Website. I'm sorry.
MR. McDONALD: And a lot of other things as well. And the word -- and "et cetera." It nowhere says the original one is limited to the internet. That is your interpretation.
MR. MIGLIORI: That's fine.
MR. McDONALD: That's not what the document says.
MR. MIGLIORI: If it came across that way, I did not mean it.
MR. McDONALD: Okay.
MR. MIGLIORI: I said internet when I meant website.
MR. McDONALD: Among other things.
MR. MIGLIORI: And et cetera.
BY MR. MIGLIORI:
Q. Okay. You had a pended order. The first thing you would do is

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go to the website, go to Google, go to the DEA website, go to licensure, et cetera. That would be the first step, correct?
A. That is a verification function.
Q. Right.
A. That -- I can't comment on verification.
Q. Well, this is -- you are receiving directly from Craig Schiavo who reports to you an SOM standard operating procedure. This is a formal document of the company, right?
A. It's a flowchart.
Q. Right. But it's a -- it's a -- it's a formal procedure. This would end up in a standard operating procedure, right? New SOM procedures, correct?
A. Correct.
Q. This isn't -- this is a formal flowchart for approval, correct?
A. For review and release.
Q. Yeah, okay.

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A. Okay.
Q. So after the website and licensure, et cetera, review, if it were not clear, it would go to a letter, correct?
A. That's what it says.
Q. So far, nothing here says get a telephone call, correct, in the flowchart?
A. Yeah, I don't -- I don't see telephone call in here.
Q. All right. If after the letter, it's not acceptable, the next step would be verification would notify your department of the pended order, correct?
A. They would notify -- "Verification notifies regulatory of the pended order."
Q. Okay. There is no reference to on-site visits for verification, correct?
A. No reference at that point.
Q. There is no reference to

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telephone interviews from verifications, correct?
A. At that point, I don't see it.
Q. It's only after the questionnaire comes back and the order cannot be released that it goes to regulatory, where regulatory will review one or all of the following: Either send an additional questionnaire, or conduct a phone interview, or conduct a site visit, or review agencies, the DEA, the Board of Pharmacy, or the police.
Do you see that?
A. I see that.
Q. So the investigation or the due diligence under this new SOM procedure in February of 2011, has all of the direct contact with the customer happening at the regulatory level, not at verifications, correct?
A. I wouldn't say all of the contact. There's definitely contact between verification and the customer in

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the second box. And you know, before it gets to regulatory, they would have had contact with the customer.

Q. By letter, according to this flowchart?

A. Well, I think they would have -- they would have called, or they could have -- they could have used any means, including a letter.

Q. I understand what they could have done. I'm actually referring to the formal procedure that's being implemented, that's being shared with you by your staff.

Under this flowchart, the only references to phone calls or on-site visits or doing an agency review like the police or the Board of Pharmacy or the DEA, is listed within the regulatory function, not the verifications function. That's what the flowchart says, correct?

A. That's what the flowchart says, but --

Q. Did -- did this get

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implemented in 2011?

A. I don't recall.

Q. At least according to this flowchart, your department was responsible for doing a phone interview or site visit or agency review, correct?

A. The regulatory department would be responsible for site visits, and they would start that with a phone interview, calling the customer to schedule and to start the process including a questionnaire.

Q. What about the DEA, the DEA review or calling the police to see if there's a police action or charge or -- that's a regulatory function, not a verifications function, under this procedure, correct?

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

Q. That's what it says here, correct?

A. That's what it says here.

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But I -- my recollection is that verifications had the licenses, as I mentioned earlier. And they had the Board of Pharmacy's information on any particular account. They maintained those licenses and the registrations, so...

Q. You are talking about a verification of license, though.

This says, "Review agencies, DEA, Board of Pharmacy, and police."

You agree there's more to due diligence than just verifying a license, correct?

A. Correct.

Q. So the Board of Pharmacy, for example, has its own procedures and censures for pharmacists, correct?

A. Correct.

Q. And that's part of the regulatory function for the regulatory affairs to look into things like investigations initiated by the Board of Pharmacy against the doctor, correct?

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A. Correct.

Q. And regulatory would have that onus here in 2011, of following up with those agencies, at least according to this chart?

A. According to this chart.

Q. And so DEA, so if the DEA -- have you ever had the experience where the DEA would call regulatory and say, "Listen, we've noticed some things in the -- in the ARCOS data that are concerning to us. Can you share with us your transactional history or your supply history with a particular customer?"

A. Yes.

Q. Would that call come into your department?

MR. McDONALD: Object to the form. Lack of foundation.

THE WITNESS: That call would -- could come into the regulatory department. It could also go into the verifications department.

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BY MR. MIGLIORI:
Q. If it comes into regulatory, is that something that you would put in the customer's file somewhere, whether it be the due diligence file or some other place in the system, in the JD Edwards system, "DEA contacted us about this doctor"?
MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: I don't recall where it was entered. But we would respond to the DEA based on their requests.
BY MR. MIGLIORI:
Q. If the DEA said they had a concern about a doctor and the doctor -- and they provided the DEA with the requested materials, would Schein then somehow note the file that this is a doctor whose ongoing orders should be viewed as potentially suspicious?
MR. McDONALD: Object to form. Lack of foundation.

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THE WITNESS: If the DEA indicated that this was an account that they had a problem with, they would have told us that.
If the DEA just wanted to see records, which occasionally happened, it was not -- you know, the DEA could have requested any -- any particular account for any reason.
BY MR. MIGLIORI:
Q. If the DEA asked for certain records because they're concerned about an account, and then that doctor put an order into Schein, would that show up in the Schein system?
MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. That the DEA has had an inquiry on this account?
MR. McDONALD: Object to the form. Lack of foundation. Asked and answered.

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THE WITNESS: I don't recall.
BY MR. MIGLIORI:
Q. Okay. But under this flowchart at least, to the extent the DEA or the police or the Board of Pharmacy were investigating a doctor, it would be the regulatory department's responsibility to do that level of due diligence on a pended order, if it escalated to this level, correct?
A. Correct.
Q. If at that level regulatory could not clear it, it would come to you, correct?
A. Correct.
Q. So if Sergio or Tina Steffanie-Oak? Did I said that right?
A. Tina Steffanie-Oak.
Q. If one of them couldn't clear it, they would bring it to your attention, correct?
A. Correct.
Q. And then if you wouldn't

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approve it, then it was a suspicious order, and you cancel the order, you probably cancel the customer too, correct?
MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. That's what the flowchart says, correct?
A. The order is deemed suspicious, and verification is notified to cancel the order.
Q. Okay. And then you would report -- this order, this pended order would be reported, though, to the DEA at the moment it triggered, right?
MR. McDONALD: Object to the form.
MR. MIGLIORI: Strike that.
BY MR. MIGLIORI:
Q. Once the shipment is placed on hold and pended, and suspicious orders were pended, would the DEA be notified at the top of this chart on Page 2?

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MR. McDONALD: I don't know, Don.
BY MR. MIGLIORI:
Q. Or further down.
MR. McDONALD: Don, you've got something different than what we're looking at.
THE WITNESS: Are you on Page 1 or --
MR. MIGLIORI: No, I'm on Page 2. That -- that's Page 3. I'm on Page 2.
THE WITNESS: I only have --
MR. McDONALD: This page.
THE WITNESS: Okay.
BY MR. MIGLIORI:
Q. I'm going back to the beginning of the review process just for a second.
A. Okay. Okay.
Q. When does DEA get, under this procedure, get notified of the order?
A. DEA would be notified, it

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says here, when -- the order is DEA and board of pharmacy are notified by regulatory affairs.
Q. Where?
A. This stuff here.
Q. So under this system, this, on the third page?
A. On this flowchart.
Q. So in 2011, when an order -- I'll go back to Page 2 for a second. When an order is pended, because of a deviation in size, frequency or pattern, by this procedure the DEA isn't notified immediately as of February of 2011?
A. The order is -- is pended here. It's not deemed to be suspicious.
Q. All right. But what we saw in the early documents that a suspicious order is one that is a deviation in size, frequency, and pattern.
A. Right.
Q. And that once pended, it needs to be reported, as Buzzeo stated in 2005, it needs to be reported

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immediately, correct?
MR. McDONALD: Object to the form. Mischaracterizes the document.
BY MR. MIGLIORI:
Q. Not -- not at the end of the month, correct?
MR. McDONALD: Object to the form. Mischaracterizes the document and the testimony. That is not what the document said.
THE WITNESS: The order is pended here. That doesn't mean it's suspicious. There's a whole review process here, we just went through.
BY MR. MIGLIORI:
Q. I'm going to -- let me give you a hypothetical so we're not confusing.
If an order is a deviation in size, it is a pended order in Henry Schein's system, correct?
A. If it's a deviation in size.

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Q. Yes?
A. Yes.
Q. An order that is a deviation in size, by definition under the CSA, is suspicious, correct?
MR. McDONALD: Object to the form.
THE WITNESS: Not necessarily.
BY MR. MIGLIORI:
Q. All right. Well, you actually had a document where you said exactly that, that we just referred to earlier.
You're saying that a deviation in size is not a suspicious order?
A. Potential, potentially. Potential. It could be. That's the review process that we're doing here.
Q. So in Schein's system, in February of 2011, Schein is not reporting immediately a deviation in size of order from prior purchasing history to the DEA

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upon discovery. Is that true?
A. We were reporting suspicious orders.
Our definition of a suspicious order, after the review is conducted and deemed to be suspicious, that's when it was reported immediately.
Q. So this flowchart is accurate, that you would not have told DEA about this until you got to this last step here of it being --
A. Deemed suspicious.
Q. -- deemed suspicious.
All right. And then it says, "Notes are placed in the system to prevent future shipments of controlled substances to this customer."
Where would that go, where would that go into the system?
A. That's a verification function. I don't know where they'd put that.
Q. Would you know where to find it if you were asked to consult on a

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particular case?
A. No.
Q. Is it in JD Edwards?
A. That's a verification question, where they put it.
(Document marked for identification as Exhibit Schein-DiBello-24.)
BY MR. MIGLIORI:
Q. I'll show you Exhibit 24. This is dated May 6, 2011.
It is a Henry Schein document produced to us. It says, "Know your customer proposal." It's May 6, 2011.
It says, "The DEA requires that we know your customer prior to shipping controlled drugs."
Do you agree at least in 2011 that was a requirement, correct?
A. Yes.
Q. That was a requirement when you started as director of regulatory affairs too, correct?

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A. Correct.
Q. "A questionnaire has been created to get detailed information on all new accounts."
Does this refresh your recollection that in the spring of 2011, a questionnaire had been created to get detailed information on new accounts?
A. I don't know what this document is. This is the first time I'm seeing it. And --
Q. If you don't know, just --
A. I don't know.
MR. McDONALD: Tell him you don't know, and we'll get out of here a lot quicker than you --
BY MR. MIGLIORI:
Q. A new field has been created in Siebel. Is that the name of the system?
A. I don't know.
Q. You never heard of Siebel?
A. No.
Q. "That will prompt the sales

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representative opening an account to ask if the practice intends on ordering control drugs."
Are you familiar with that new process on new customers?
MR. McDONALD: Object to the form.
THE WITNESS: I'm not familiar with that.
BY MR. MIGLIORI:
Q. "If so, the rep will send questionnaire via fast fax or e-mail to the customer."
Are you familiar with that process?
A. I don't -- no.
Q. "The customer will fill out the document and return to verifications prior to any controlled drugs shipping to the office. The average number of new accounts ordering controlled substances per day is 6 to 12."
Is that your recollection, how many new customers were being

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onboarded daily?
A. I don't recall.
Q. And you don't recall if verifications implementing this new -- this new system, correct?
A. I don't recall this --
Q. It's called a proposal?
A. This proposal.
Q. "The process will increase the number of pending orders if the customer does not send the document back prior to the order being placed."
Do you recall an increase in pended orders as a result of a new process of sending out due diligence letters for new customers?
A. Order -- there was an increase in pended orders.
Q. Yeah. Do you recall there being any such process --
A. I recall --
Q. -- put in place where pended orders increased as a result?
A. I vaguely recall that pended

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orders were increasing because of the process changes generally.
Q. As you sit here today, do you recall whether this actually -- this proposal actually got implemented for new customers?
A. I'm not familiar with this proposal. Sorry about that.
Q. June of 2012, you haven't left -- you haven't left Schein yet, correct?
A. That's correct.
Q. You left in September?
A. October.
(Document marked for identification as Exhibit Schein-DiBello-25.)
BY MR. MIGLIORI:
Q. Henry Schein produced to us a June 12, 2012, letter from Joe Rannazzisi. Would this be a letter that you would have received in your role as director of regulatory affairs in June of 2012?

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A. I would have received this.
Q. And the purpose of the letter is to remind controlled substance manufacturers and distributors of their responsibility to inform DEA of suspicious orders in accordance with the Controlled Substances Act. Do you recall this letter?
A. I don't recall this specific letter.
Q. You'll see that it's Joseph Rannazzisi again, the deputy assistant administrator, office of diversion control. You don't -- you do not recall this?
A. I don't recall this particular letter.
Q. Okay. But this is something you would have received --
A. I would have received -- I would have received it.
Q. Were you still there in October 15, 2012?
A. 2012, October 15th. I had

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resigned. That was my last week, actually. I think my last -- I'm not sure. I might have left before the 15th. It was right about that time. I don't remember the actual resignation date. But it was -- I might have left by then, or it was my last week. Yeah, I gave three weeks' notice.
Q. Do you recall learning about a doctor in California that was linked to drug-related deaths that was receiving a supply of controlled substances from Henry Schein in January of 2012?
A. Doctor related to controlled substances death in California.
Q. Yeah. Being forwarded a news article by your staff about doctor-related -- opioid-related deaths of one of your customers.
(Document marked for identification as Exhibit Schein-DiBello-26.)
BY MR. MIGLIORI:
Q. The article is on the third

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page. It's entitled, "California doctor linked to drug deaths arrested for trafficking commonly abused painkillers."

The copyright is 2012. The e-mail is forwarding it, if you go to the second page, start on January 6th of 2012. Randy Stader, and eventually it gets sent up to you as it's being forwarded.

Do you recall this?

A. Not specifically.

Q. On the first page, Craig Schiavo is writing to Sergio and to you saying -- well, regarding this article, "FYI, we have a good amount of sales to this doctor," on January 9, 2012. And your response to that, can you read that, Monday, January 9th of 2012, starting with, "Why didn't"?

A. "Why didn't a questionnaire go out? Did the orders pend? Who reviewed/released? How far over threshold? Did they get a just letter? Thanks."

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Q. What is a just letter?

A. I would say that's a justification letter, short for justification.

Q. So that's the due diligence letter?

A. We called it a justification letter.

Q. But --

A. Part of the due diligence process.

Q. Okay. And so the response to your e-mail was, "Mike, I followed up with Shaun on this, and he's putting all the information together and will send it to me today. He did tell me, though, that the account did pend four times. We never requested a questionnaire or justification letter. Once I receive everything I will send you the information."

Do you recall finding out about this?

A. I don't recall what the

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final result of this review was. I don't remember this specific case.

Q. As you sit here today, you don't remember this at all?

A. I don't remember this particular doctor.

Q. You would agree with me that if the account pended four times, that under that flowchart at the very least, a questionnaire, justification letter should have gone out to the doctor?

A. I would have to take a look at the policy, the procedure we have in place at that time. And I would have to look at the file that Craig was putting together.

Q. If you look at the flowchart that I just went through with you, you would agree with me that if the account pended, short of somebody in verifications unilaterally releasing it, the next step would be to get a justification letter, correct?

MR. McDONALD: Object.

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BY MR. MIGLIORI:

Q. That's the procedure in place?

MR. McDONALD: Object to form. That's an improper hypothetical. That flowchart, are you representing that that flowchart was in place at the time that the orders were made?

MR. MIGLIORI: You can read the e-mail. You don't need to testify either. But the e-mail on top talks about the new procedure. It's called the new procedure.

MR. McDONALD: Object to the form. Improper hypothetical. Assumes facts not in evidence.

BY MR. MIGLIORI:

Q. If you look at the procedure that was sent to you from Sergio Tejeda that predates this, you would agree with me that the first step of the pended orders that are referenced here -- and this pended four times. The first step

in the flowchart would be from somebody from verifications looking at the order and going to the website, the Google, the DEA website, licensure, et cetera. That would be the first step of a review for a pended order, correct?

MR. McDONALD: Same objections.

THE WITNESS: Correct. According to the procedure.

BY MR. MIGLIORI:

Q. And short of them clearing, somebody in verifications clearing based on that level of review, the next step for the doctor in a pended order would be for the doctor to get a justification letter, correct? You can look at the document if you'd like.

A. Can I see the document again?

Q. Sure. It's right in front of you. It's the last exhibit, or second-to-last exhibit.

A. Okay.

Q. The next step is a justification letter being sent out to the doctor, correct, from verifications?

A. Verification, that's what the procedure says, would send justification letter.

Q. Okay. So as Craig is relating to you that this account had four pended orders, but we never requested a questionnaire or justification letter. If that's a true statement, you would agree with me that that's a violation of your own standard operating procedure for due diligence for this customer, correct?

MR. McDONALD: Objection to form. Improper hypothetical.

THE WITNESS: I don't know what the final analysis in this particular case was.

Craig says, "Once I review everything, I will send you the information." So there may have been other communication in this

particular case between verifications and the doctor.

BY MR. MIGLIORI:

Q. Okay. But my question to you was, assuming that that statement is correct, that would have been a violation of your standard operating procedure to not send justification letters out to this doctor with four pended orders, correct?

MR. McDONALD: Same objections.

THE WITNESS: A violation of this procedure?

BY MR. MIGLIORI:

Q. Yeah. If the next step, as we just went through, was to get a letter, the due diligence of a pended order is go review the licensure and websites, and if not cleared, send out a justification letter for the customer to fill out, correct?

A. There could have been another way of clearing it through

communication --

Q. Understood.

A. -- with verification. And the doctor -- which I can't -- I can't comment on. That was a verification function.

Q. I'm asking you based on the procedure that's in front of you, these pended orders should have received justification letters, correct?

MR. McDONALD: Object to the form.

THE WITNESS: That's what the procedure says.

BY MR. MIGLIORI:

Q. Okay. And at least based on the e-mail that's in front of you right now, that didn't happen for the four pended orders, correct?

A. I don't recall the final analysis when Craig put everything together. Maybe at that time they didn't have it. But I don't -- I don't remember the final file.

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Q. All right. I'll show you another follow-up on it. It's Exhibit 27.

(Document marked for identification as Exhibit Schein-DiBello-27.)

BY MR. MIGLIORI:

Q. Here's some more detail. Jim Mullins writes to others. You're not included in this one. Jim Mullins says Shaun Abreu -- who is at this point head of verifications, correct. 2012?

A. I'm not sure of his title. He was the head of verifications. I don't recall when he became the supervisor of that group. I'm not sure of his title.

Q. He was at one point supervisor of verifications, right?

A. At one point, I believe he or Lisa Madeline, I think, were. I'm not sure which one is the actual supervisor.

Q. Well, Lisa is also copied here.

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A. Okay.

Q. And Shaun writes to others -- and you'd agree with me that a justification letter is sent out in the verifications department, not a regulatory, correct?

A. Verifications department sends justification letter.

Q. Right?

A. Right.

Q. And Shaun writes and says, "Jim, of the 14 orders that were placed, four of them pended. We pended orders on August 25, 2010; November 19, 2010; January 7, 2011; and January 31, 2011.

"I agree it does appear to be a high volume, and the account was listed as a family medical clinic, which may have caused more orders to be released."

Why would being listed as a family medical clinic override four pended orders?

A. I don't know.

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Q. Is there anything in your history as director of regulatory affairs that would say that a listing of a family medical clinic is a justified override of a pended order?

A. I don't recall.

Q. "The account is also coded as a multi-special private practice."

Is there anything about coding the account as a multi-special private practice that allows for verifications at the first level to release a pended order?

A. Well, accounts were categorized based on their practice types. That was all part of the -- the review process.

Q. My question is, was there anything about that categorization that should have had somebody at the first level of verifications release four pended orders over a course of six months?

A. I don't --

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MR. McDONALD: Hang on. Object to -- object to the form. Lack of foundation.

THE WITNESS: I don't know.

BY MR. MIGLIORI:

Q. You don't know.

If you go a little further down. Jim writes to Shaun and says, "Shaun, did orders pend? Looks like a lot in a short period of time?"

And then prior to that, Shaun wrote and said, "I ran the ORD881."

What does that mean? Do you know?

A. I think that was a report on the account.

Q. He ran it from January 6th of 2007 to January 6th of 2012. "And it looks like he only purchased controlled substances from us for a short period starting in July of 2010 to January of 2011. Attached is the report. We don't have a suspicious order monitoring questionnaire on file for the doctor."

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Would you agree with me that that's not consistent with the new customer recommendations of Cegedim?
MR. McDONALD: Object to the form.
BY MR. MIGLIORI:
Q. To have a new customer without a questionnaire on the file?
MR. McDONALD: Object to the form.
THE WITNESS: I can't comment on the verification function without seeing the -- the file.
BY MR. MIGLIORI:
Q. Would you agree that by 2012, your last year as director of regulatory affairs, that if there is no questionnaire in a customer file, whether it be as a new client questionnaire, or an ongoing questionnaire, that that is not consistent with your standard operation -- operating procedures for due diligence; every customer should have a

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questionnaire in their file, correct?
MR. McDONALD: Object to the form.
THE WITNESS: That's the general rule. There may have been an exception for this particular account, for this particular situation. Not everything is black and white.
And I can't comment without seeing what else the verification group did to satisfy themselves that they were okay proceeding.
BY MR. MIGLIORI:
Q. Just to put in perspective, this news article says, "Diaz, a doctor, hasn't been charged in connection with the deaths which remain under investigation. He is accused of illegally prescribing large amounts of pain killers to patients who didn't need the drugs and for accepting sexual favors as payment from some women."
Now, is there anything about

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that doctor that you think would have exempted him from the due diligence requirements of having a questionnaire in the file?
MR. McDONALD: Object to the form.
THE WITNESS: This was a verification process. I can't comment on their review of this Dr. Diaz.
BY MR. MIGLIORI:
Q. You would agree that if that escalated to you as director of regulatory affairs, you would hope to, and expect to see at least a customer questionnaire in your file, correct?
MR. McDONALD: Object to the form. Improper hypothetical.
THE WITNESS: I would expect to see documentation that satisfied the verification review process.
BY MR. MIGLIORI:
Q. Including the customer

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questionnaire, correct?
MR. McDONALD: Object to the form.
Object to the form.
THE WITNESS: That's one way of documenting their review of this account.
BY MR. MIGLIORI:
Q. In 2012, the customer questionnaire was required for all customers, correct?
A. I don't recall when it went into place. And -- and if there were exceptions or other methods of verifying the doctors' status.
(Document marked for identification as Exhibit Schein-DiBello-28.)
BY MR. MIGLIORI:
Q. Let me show you Exhibit 28.
This is a year after you left, but this relates to the "know your customer" requirements.
You talked earlier about

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Tina Steffanie-Oak, right? She worked for you -- or she worked for Sergio Tejeda under you while you were director of regulatory affairs, correct?

A. Correct.

Q. And she has a PowerPoint presentation here that was produced to us entitled, "Individual Opportunity/Issue," presented by Tina Steffanie-Oak, where she puts on the first line, "Are we in substantial compliance with the DEA's suspicious order monitoring 'know your customer' regulations?"

And she puts in the first bullet point, "We do not have 'know your customer' due diligence for approximately 60 percent of our customers. Remaining 40 percent has varying degrees of due diligence. Files are inconsistent."

Were you aware that as of the time that you left Henry Schein, that 60 percent of the customers that you were servicing did not have due diligence in their files?

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A. No.

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

Q. Were you aware that of the 40 percent that had some due diligence, that it was varying degrees of due diligence, and they were not consistent with any standard operating procedure?

MR. McDONALD: Object to the form.

BY MR. MIGLIORI:

Q. Were you aware of that?

MR. McDONALD: Object to the form.

THE WITNESS: No.

BY MR. MIGLIORI:

Q. Is that alarming to you, that 60 percent of the customers, as of 2013, had no due diligence, "know your customer" due diligence in their files? Is that surprising to you?

MR. McDONALD: Object to the form.

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THE WITNESS: This is the first time I'm seeing this. I'm not familiar with this report, so I -- it's a large number. I agree.

MR. MIGLIORI: Why don't we take a break and I'll look at what I got and we'll wrap up.

THE VIDEOGRAPHER: Stand by please. The time is 4:44 p.m. Off the record.

(Short break.)

THE VIDEOGRAPHER: We are back on the record. The time is 4:54 p.m.

BY MR. MIGLIORI:

Q. Who is Stanley Bergman?

A. Who is Stan Bergman?

Q. Yeah.

A. He is the chairman and COO of Henry Schein.

Q. Okay. And that was his position in 2008?

A. That was his position.

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Q. Was that his position in 2008?

A. Yes.

(Document marked for identification as Exhibit Schein-DiBello-29.)

BY MR. MIGLIORI:

Q. Exhibit 29. This is a news article that Stan Bergman forwarded to your supervisor, Len David, about a doctor. "Forest City Doctor Has Been Charged With Administering Controlled Substances Without Proper Recordkeeping." And it talks about, "The investigation beginning in December of 2007 following receipt of a DEA substance control ordering form that belonged to Cosby. The form showed purchase of narcotics Demerol and Dilaudid, and further investigation determined Cosby had made 40 purchases of controlled substances from Darby Dental Supply in Memphis, Tennessee and Henry Schein in Indianapolis."

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Do you recall this news article?
A. I don't recall this specific news article.
Q. It says, "While Cosby was listed in good standing on the Pennsylvania Department state website, DEA discovered that Cosby was given one year probation in 1976 on 45 counts of issuing a narcotic prescription to drug dependent persons and six counts of dispensing narcotic prescriptions to a drug dependent person, according to the criminal complaint."
You'll agree with me that somebody that maintains an active good standing license, does not necessarily in and of itself show that the person should be somebody that should be receiving controlled substances, correct?
MR. McDONALD: Object to the form.
THE WITNESS: It's a broad statement. In general, I agree.

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BY MR. MIGLIORI:
Q. In a robust due diligence system, would you agree that you would want to at least know at Henry Schein of the 45 counts of narcotic prescription dispensing and the six counts of dispensing narcotic prescriptions to drug dependent people, at least in the due diligence process, you'd want to know about those prior probation convictions?
A. Correct.
Q. And that's something that should be part of a good onboarding of a new customer process?
A. Should be.
Q. This was escalated to you where Len wrote to you, after receiving it from Stan Bergman, and he wrote, "Knew this would trigger SB's inquiry. Ideas regarding response?"
And your response on October 1st, 2008, was, "Regulatory and verifications were both involved with DEA Agent Jackson during investigation of

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Dr. Cosby. Henry Schein and Darby were not the target of the investigation and the information requested was provided in a complete and timely manner. Our verifications protocol did confirm that the doctor did indeed have a valid state license and DEA registration and was not ordering excessive quantities. Doctor's account has been restricted to block pharma and controlled substances shipments."
You'll agree with me that just verifying that having a valid state license and DEA registration and not triggering an excessive order is not in and of itself due diligence or complete due diligence with respect to this customer, correct?
MR. McDONALD: Object to the form.
THE WITNESS: Generally speaking, that's correct.
BY MR. MIGLIORI:
Q. Okay. And as a result of --

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even though this doctor had a valid license, even though this doctor had a valid DEA registration, and even though the system did not trip an excessive order in the system, you did go ahead and suspend and cancel this order, this doctor's ability to order controlled substances from Henry Schein as a result of this news article, correct?
A. We restricted the account. The doctor's account has been restricted to block pharmaceuticals and controlled substances.
Q. You say, "Although we have sophisticated and comprehensive suspicious order monitoring systems/procedures, it is extremely difficult, if not impossible, to identify and police practitioners who maintain valid state and federal licenses and decide to dispense controlled substances to drug-dependent patients."
And that's an -- that's an understatement of your obligation at

Henry Schein to know your customer, isn't it?

MR. McDONALD: Object to the form.

THE WITNESS: I don't remember this particular doctor. Again, I would need to look at the file that would have information regarding the drug-dependent patients and the doctor's interaction with his patients and what we did at the time. I don't recall.

BY MR. MIGLIORI:

Q. Okay. Certainly it was within regulatory -- at least in the later schematic of the procedure for due diligence, it certainly would have been in regulatory's realm, the regulatory affairs department, to do the kind of due diligence to check with DEA, Boards of Pharmacy and police to see whether or not this kind of doctor had any prior issues relating to controlled substances,

correct?

MR. McDONALD: Objection.

BY MR. MIGLIORI:

Q. That would have been a regulatory inquiry, correct?

MR. McDONALD: Objection to form.

THE WITNESS: It would be once the doctor's orders pended.

BY MR. MIGLIORI:

Q. And you can't tell by looking at this document whether or not any such inquiry was ever done at Henry Schein, correct? You just can't tell without seeing the due diligence file?

A. Correct. I need to see the complete file.

(Document marked for identification as Exhibit Schein-DiBello-30.)

BY MR. MIGLIORI:

Q. Let me show you Exhibit 30. It's an e-mail exchange again that you're mentioned on. The cover e-mail is

November 18, 2011, and it involves Melodie Steele. Who is she?

A. Melodie Steele was an operations manager at the Indianapolis facility.

Q. Okay. She writes to you and to Sergio and says, November 18, 2011, "The Iowa Board of Pharmacy found probable cause to file charges against Henry Schein for supplying C-II morphine to Des Moines University who was without a valid controlled registration. Notice to appear in January of 2012."

Do you recall this happening?

A. I don't recall this specific.

Q. Would you have been the person who appeared before the board of pharmacy if you received this kind of notice?

A. I did not appear. I don't -- I don't remember appearing.

Q. Attached to it is the Iowa

Board of Pharmacy's action against Henry Schein, statement of charges. Do you recall the Attorney General or the board of pharmacy in Iowa finding that Henry Schein had dispensed morphine to the university without a valid license?

MR. McDONALD: Object to the form.

THE WITNESS: I don't recall.

BY MR. MIGLIORI:

Q. It says, "This matter may be resolved by settlement agreement." Do you know whether or not such an agreement was entered into?

A. I don't recall.

Q. So you do not recall, as you sit here today, the -- the outcome of this action, do you?

A. I don't recall the outcome.

Q. Is this something that would have been handled by the department by the -- the Department of Regulatory Affairs?

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A. This probably would have gone to legal. I would have forwarded it to legal.
Q. Okay. And the charge includes, "From December 19, 2008, through August 31st of 2009, respondent supplied a total of 800 milliliters of Schedule II morphine sulfate injection to Des Moines University. At the time respondent supplied the morphine sulfate injection to Des Moines University, the university did not have a valid controlled substances registration submitted by Des Moines University to possess the morphine sulphate injection."
If that is the charge, where would the system have failed?
MR. McDONALD: Objection to form.
BY MR. MIGLIORI:
Q. And by system, I mean Henry Schein's system for verification or compliance.
A. That would be a verification

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function.
(Document marked for identification as Exhibit Schein-DiBello-31.)
BY MR. MIGLIORI:
Q. Exhibit 31. It's an e-mail exchange just before you are leaving, between Shaun Abreu and Craig Schiavo.
Craig Schiavo worked for you at this point, correct?
A. Worked for Sergio.
Q. Okay. But worked within regulatory affairs?
A. Correct.
Q. On January 31st, the bottom e-mail on the first page says, "Hi Craig, please see the attached file from the "know your customer" proactive process. This doctor was self-medicating, but he did 31,000 in sales for 2011. I had him send us a justification stating that he will no longer order the product to self-medicate, and that all future controlled substances orders will be for

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patient use. Are you okay with reinstating? See attached file."
Is that an appropriate use of the "know your customer" system?
MR. McDONALD: Object to the form.
THE WITNESS: An appropriate use of the know your customer?
BY MR. MIGLIORI:
Q. Yeah. We'll break it down for you.
Should Shaun Abreu instruct a customer that they should fill out a form saying they'll no longer self-medicate? Is that consistent with the due diligence "know your customer" obligations of Henry Schein?
MR. McDONALD: Object to the form. Lack of foundation.
THE WITNESS: I can't speak to what Shaun Abreu told the customer.
BY MR. MIGLIORI:
Q. Is self-medicating permitted

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under the Henry Schein controlled substance policies and procedures?
A. Self-medicating is frowned upon. And it's one of those areas that we reviewed carefully and would not -- would not approve.
Q. Would it be appropriate for Shaun Abreu to take a doctor that was self-medicating, but since he did $31,000 in sales for 2011, he had him fill out a justification letter stating that he'll no longer self-medicate, is that an appropriate way of using the justification letter process?
MR. McDONALD: Object to the form.
THE WITNESS: I can't comment on Shaun -- what -- you know, I don't know the -- the interaction between Shaun and the doctor just based on, you know, this e-mail.
BY MR. MIGLIORI:
Q. Craig wrote to Shaun and

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said, "I am okay with reinstating. Do you think we should send this to the DEA as a follow-up to our reporting letter?"

And Shaun wrote back and said, "We never reported to DEA, it was part of the proactive process. I can simply reinstate the customer."

Based on what's on this e-mail, is that an appropriate use of Schein's justification, due diligence process, proactive process?

MR. McDONALD: Object to the form.

THE WITNESS: I don't -- I would need to see the -- the rest of the file to -- to comment on it.

BY MR. MIGLIORI:

Q. Was it enough at Henry Schein for a doctor to just simply say I'll stop self-medicating, to justify continuing to sell in the order of $31,000 per year --

MR. McDONALD: Object to the

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form.

BY MR. MIGLIORI:

Q. -- to the customer?

MR. McDONALD: Object to the form.

THE WITNESS: A customer would have to explain his circumstances in order to proceed with the order.

BY MR. MIGLIORI:

Q. If the doctor is found to have been self-medicating, isn't that a reportable event to DEA?

MR. McDONALD: Object to the form.

THE WITNESS: I don't recall DEA's position on self-medicating. I don't believe it's technically illegal.

BY MR. MIGLIORI:

Q. Okay. And would it be up to Shaun Abreu to make the decision not to report within the Henry Schein system in 2012?

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A. It depends on what -- what happened with the account and the -- and the doctor.

Q. Apparently the doctor was cleared to purchase as long as he promised not to self-medicate, based on the e-mail. Is that an appropriate -- in the decision tree, is that an appropriate decision for Shaun Abreu to be making, not to report that kind of self-medicating event to the DEA?

A. If Shaun was the manager of the verification group at the time, that was his decision. But again, based on his interaction with this particular doctor.

Q. Does it trouble you that the verification, at least on the face of his e-mail, was that the account was a $31,000-a-year account?

MR. McDONALD: Object to the form.

THE WITNESS: I would not factor in with the $31,000

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account.

BY MR. MIGLIORI:

Q. Would you agree with me on the face of the e-mail, he did?

MR. McDONALD: Object to the form.

THE WITNESS: I don't know that. I can't tell just based on this e-mail what else was there.

BY MR. MIGLIORI:

Q. He certainly took the time to bring it to the attention of your department, that it is a $31,000 account, correct?

A. He forwarded it to Craig.

Q. Who worked for you or worked for Sergio?

A. Worked for Sergio.

(Document marked for identification as Exhibit Schein-DiBello-32.)

BY MR. MIGLIORI:

Q. Let me show you Exhibit Number 32. Were you aware that for --

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that during the period of time that you were director of regulatory affairs, that Henry Schein had not been reporting sales of controlled substances to the Ohio Board of Pharmacy as required by Ohio law?

MR. McDONALD: Object to the form. Assumes facts not in evidence.

THE WITNESS: I was not aware.

BY MR. MIGLIORI:

Q. This is a letter dated November 9, 2012. You had just left a month earlier, correct?

A. Correct.

Q. And Sergio Tejeda at this point is listed as director of regulatory operations and compliance. Is that a promotion from where he was before?

A. Correct.

Q. And he writes to the Ohio State Board of Pharmacy in November of 2012, saying that "the purpose of this

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letter is to notify the Ohio Board of Pharmacy of an issue that we recently discovered while conducting a routine internal review of our operations. During the course of our internal review we realized that Henry Schein has been underreporting sales of controlled substances to the Ohio Board of Pharmacy as required by the state's Prescription Monitoring Program, PMP. The reports included sales of products containing tramadol and carisoprodol, but do not include sale of other controlled substances. We believe the underreporting error was due to misinterpretation or miscommunication of the state requirement that happened during the implementation of our computer automated reporting system."

Did that ever get brought to your attention while you were director of regulatory affairs?

A. No, I don't recall that. I wasn't paying attention.

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Q. It says that, "To date, Henry Schein has consistently filed reports on a timely basis as required by the PMP, and prior to the discovery of this issue, Henry Schein was not aware the reports were incomplete. Please be reassured that there was never any intent to avoid or circumvent the customers obligation under Ohio state law, and as an act of good faith, Henry Schein is providing all controlled substance sales information which was mistakenly omitted for the previous two years."

So were you -- would that have been a function of regulatory affairs to make sure that Henry Schein was in compliance with Ohio reporting requirements under the prescription monitoring program, the law in the state of Ohio for those two years?

A. It sounds like a verification report.

Q. So reporting of transactions of sale of controlled substances from

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Henry Schein from 2010 to 2012 was the function of the verifications department and not the regulatory affairs department?

A. That's what it sounds like, yeah.

Q. And yet this letter is being written from the regulatory affairs department, correct?

A. That's correct, because regulatory would interact with the agency. But the actual reporting, just like the ARCOS and other reports, are verification functions.

Q. Okay. And you agree with me that reporting is an essential part, is an integral report of the effective detection and prevention of diversion, both at the state and federal levels, correct?

MR. McDONALD: Object to form.

THE WITNESS: I would agree.

BY MR. MIGLIORI:

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Q. Go ahead.
A. I would agree.
MR. MIGLIORI: Last document. And we'll get your lawyer out of here.
MR. McDONALD: I actually need to get on a call. I'll pass it on.
MR. MIGLIORI: I won't ask anything objectionable.
This is the last document.
BY MR. MIGLIORI:
Q. We got a little late start with the 10:30 time. I'm trying to get us out of here on time.
(Document marked for identification as Exhibit Schein-DiBello-33.)
BY MR. MIGLIORI:
Q. Exhibit Number 33. Jeff Peacock was your successor?
A. Correct.
Q. And this is a December 19, 2012, assessment, internal assessment of

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the regulatory affairs/verifications department. Do you see that?
A. Okay.
Q. And so the assessment team, the DEA assessment team, and it was comprised of -- and this is what Jeff Peacock testified to, Sergio Tejeda, Tina Steffanie-Oak and Ken Romeo. Is that consistent with your recollection?
A. I'm not familiar with this report. This is the first time I'm seeing it. And it's --
Q. I'm not asking about the report. I'm just asking the team. Do you remember there being a DEA team that Sergio headed up with Steffanie-Oak and Ken Romeo from your department?
A. Sergio and -- Sergio was the head of the DEA team, yes.
Q. Okay. And Steffanie and Ken worked for him, correct?
A. Tina worked and Ken worked for Sergio.
Q. I'm sorry, Tina. And so Ken

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Romeo wrote to the -- from regulatory affairs wrote to Jeff Peacock, the now director of regulatory affairs about two months after you -- I'm sorry, about a year --
A. Over a year.
Q. -- after you left about the state of suspicious order monitoring program, correct?
A. Okay. That's what it says.
Q. So the date here, although it says December 19, 2012, it's actually the 2013 verification team. Do you see that, the dates?
A. Okay.
Q. I just want to orient you.
A. Okay.
Q. "The assessment is a result of a cooperative effort of the regulatory and verification teams that looked into the identification of controlled substances and/or a specific combination of controlled substances that might potentially place Schein in a high risk

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category as a distributor of controlled substances for DEA regulatory actions."
Did you ever have such assessments reported to you while you were director of regulatory affairs?
MR. JONES: Object to the form.
THE WITNESS: No.
BY MR. MIGLIORI:
Q. It says the material -- the other purpose was, "The materiality of controlled substance transactions in dollar thresholds and active product ingredients thresholds, computer system errors inherent or not presently accounted for, unintentional misrepresentations or omissions, risk control statistics as they related to the level of training and potential errors, and known DEA hot buttons, such as current street trends."
Were you ever apprised of the effectiveness of the new SOM program that was implemented in October of -- I'm

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sorry, 2009 from internal audits?
MR. JONES: Object to the form.
THE WITNESS: No.
BY MR. MIGLIORI:
Q. All right. This team, that team of Sergio Tejeda, Tina Steffanie-Oak, and Ken Romeo, they existed as a team before you departed as director of regulatory affairs, correct?
A. Yes.
Q. Okay. They had certain findings. One of the findings was that, "The current suspicious order monitoring system" -- again this is December 2013 -- "appears to utilize a regression formulated statistical mode as a basis for normalizing prescribing and purchasing patterns for controlled substances and dangerous prescription drugs resulting in product release." It says here, "The real problem lies in the fact that our suspicious order monitoring system provides us only a mirror image of

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our own business model. Our system has not been checked against a neutral nationally recognized medical database to crosscheck its validity as truthful and accurate."
Had you ever had any observations or findings that said that the suspicious order monitoring system that you had in place was not real world oriented?
MR. JONES: Object to the form.
THE WITNESS: No.
BY MR. MIGLIORI:
Q. The Schein regulatory affairs team found that, "Current suspicious order monitoring parameters of market segment, practice type, and practice specialty do not cross-reference normal clinical drug utilization" -- "utilization patterns."
Was that observation or finding ever presented to you while you were director of regulatory affairs?

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A. No. I don't even know what that means.
Q. Okay. Was it ever told to you that the suspicious order monitoring system as of 2013 was overburdened with human intervention?
A. No.
MR. JONES: Object to the form.
THE WITNESS: No.
BY MR. MIGLIORI:
Q. And was it ever told to you that the risk level for DEA enforcement action was high because of the current computerized suspicious order monitoring system being dated?
MR. JONES: Object to the form.
THE WITNESS: No.
BY MR. MIGLIORI:
Q. Second finding of Sergio Tejeda and his team was that, "The individual account thresholds for controlled substance purchase may be

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adjusted by verifications without regulatory and/or medical guidance which could result in an inappropriate product release." The risk level for DEA enforcement level was high.
Were you ever told that the verifications adjustments subjected the company to a high risk of DEA involvement?
MR. JONES: Object to the form.
THE WITNESS: No, I was not.
BY MR. MIGLIORI:
Q. Were you aware that as of 2013 the regulatory affairs department at Henry Schein thought that, "The 'decisionmakers' in the verifications department lacked the medical training and qualifications to release controlled substances without regulatory or medical guidance in some instances"?
Had that observation ever been made to you?
A. No.

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Q. It says, "An example, a product release decision can be made solely within the verification team without a secondary check. Justification letters submitted to Schein by physicians or accounts requesting controlled substances are not reviewed currently by medically trained personnel."

Was that true as of the time that you left, that these justification letters were not being reviewed by medically trained personnel?

A. Justification letters were processed by the verifications group. I'm not aware of any medical professional in that group.

Q. Okay. "In fairness, they are doing the best they can with the limited training that they have received, and many of our verifications colleagues are new to the particular position of decisionmaker. Also, internal documentation such as account notations performed by suspicious order teams is

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not revealed to regulatory on a regular basis."

Did you have any observations or findings shared with you before you left Schein that a lot of these internal decisions were being made by folks underqualified and those decisions were not being shared on a regular basis with your department?

MR. JONES: Object to the form.

THE WITNESS: No.

BY MR. MIGLIORI:

Q. It goes on to say that, "The current gut feeling approach, while laudable, leaves Schein exposed. Operating within a closed loop is usually dangerous. During assessment process, accounts were identified which needed further regulatory scrutiny but were trapped with the closed loop."

Did anyone express concerns to you about the current system that we showed in the diagram, the flowchart of

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decisionmakers, that that as a result led to orders that should have gotten regulatory scrutiny that didn't?

MR. JONES: Object to the form.

THE WITNESS: No.

BY MR. MIGLIORI:

Q. Sergio Tejeda and his team in regulatory affairs also found that, "The accounting data reported to regulatory and verification underwriters as total sales may be materially misstated."

Were you aware of any accounting issues before you left as director of regulatory affairs as to total sales in their reporting?

MR. JONES: Object to the form.

THE WITNESS: No.

BY MR. MIGLIORI:

Q. As of the time you left as director of regulatory affairs, were you aware that Henry Schein had a standard

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operating procedure that allowed for a customer to get a courtesy release of controlled substances three times before an account was required to have full documentation for medical need?

MR. JONES: Object to the form.

THE WITNESS: No.

BY MR. MIGLIORI:

Q. Were you aware that the suspicious order monitoring system in 2013, at that point still failed to account for two potential deviate order patterns?

MR. JONES: Object to the form.

THE WITNESS: I wasn't there in 2013.

BY MR. MIGLIORI:

Q. Okay. As of the time that you left in October of 2012, were you aware that the suspicious order monitoring system that had been put in place and enhanced through the time of

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your departure, still failed to account for two potential deviate order patterns?
MR. JONES: Object to the form.
THE WITNESS: No.
BY MR. MIGLIORI:
Q. And as of December 2013, a year after you left as director of regulatory affairs, the internal regulatory affairs DEA compliance team recommended in the short-term that Henry Schein enhance communication with the verifications department, provide additional medical training to verification decisionmakers, and provide additional training relative to account due diligence techniques.
Those were still issues that required enhancement and improvement a year after you left as director of regulatory affairs. Were you ever made aware of that?
MR. JONES: Object to the form.

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THE WITNESS: No.
BY MR. MIGLIORI:
Q. And that the long-term recommendation of the regulatory affairs team was that it was required that a more proactive involvement by regulatory in the API and SOM systems on a continual basis, that at a year after you left as director, Sergio Tejeda was recommending to Henry Schein that regulatory play a more proactive role in the suspicious order monitoring program at Henry Schein.
MR. JONES: Object to form.
BY MR. MIGLIORI:
Q. Were you aware of that?
MR. JONES: Object to form.
THE WITNESS: I was not aware of that.
MR. MIGLIORI: Sir, I appreciate your time. I think that's all I have. I appreciate it.
THE WITNESS: Thank you.
MR. JONES: We'll reserve our questions.
THE VIDEOGRAPHER: Stand by please. This marks the end of today's deposition. The time is 5:28 p.m. Off the record.
(Excused.)
(Deposition concluded at approximately 5:28 p.m.)

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CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, MICHAEL DiBELLO, have the opportunity to read and sign the deposition transcript.

MICHELLE L. GRAY,
A Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter and Notary Public
Dated: February 22, 2019

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 337, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
MICHAEL DiBELLO DATE

Subscribed and sworn to before me this
_____ day of _____, 20____.
My commission expires:_____

_____
Notary Public

LAWYER'S NOTES

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